Canada. Commission of Inquiry on the Pharmaceutical Industry
Compulsory patent licensing of drugs in Canada: have the full price benefits been realized? (background study)

Background Study

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Commission of Inquiry on the Pharmaceutical Industry

Canada

Compulsory Patent Licensing of Drugs in Canada: Have the Full Price Benefits Been Realized?

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I INTRODUCTION

In 1969 an amendment to the Canadian Patent Act allowed compulsory patent licensing of drugs.[1] Each license permitted the owner to manufacture and/or import a particular drug for which the patent was still extant. A royalty fee was set at four per cent of the licensee's selling price. Licenses were issued almost as of right. By 1983, 181 licenses had been granted for 58 prescription drugs.[2] Licensees typically imported the bulk active ingredient, the raw material, with final dosage preparation, the end product, taking place in Canada. The licensees tend to be the smaller, often Canadian-owned firms, not the large multinational drug firms which dominate the industry, owning most of the patents and with whom the licensees had to compete.

The passage of the 1969 amendments was designed by the federal government, with the support of several of the provinces, to stimulate price competition at the level of the manufacturer via the entry of low-priced licensee products. A series of complementary measures and policies were introduced by virtually all provincial governments in the 1970s and early 1980s, at the retail level, with the objective of facilitating the passing-on of such price reductions to the consumer.[3]

A series of studies have documented that the expected price reductions at the level of the manufacturer have indeed taken place.[4] However, whether such price reductions have been

passed-on to the consumer is much more of a moot point.[5] The paucity of studies in this area reflects, in large part, the complexity of the retail market, which not only differs between provinces, but also quite markedly both within a province and over time. The purpose of this study is to rectify this gap in our knowledge.

The paper is organised as follows. In the next section, II, we outline and define the consumer and the nature of the market in which consumers make their purchasing decision. Given this market, we attempt in section III to predict or rank the degree to which the consumer has been able to realise the full benefits of compulsory licensing in various retail markets. Section IV then sees how closely these a priori rankings agree with actual experience and thus enhance our understanding of the determinants of retail drug prices in Canada. Finally, in section V, some conclusions and a brief summary is presented.

II THE MARKET FOR DRUGS

2.1 Introduction

The market for drugs is quite different from the stylized picture presented in elementary economic textbooks or even that to which consumers are frequently exposed in everyday life. Such markets typically have a number of important characteristics. On the demand side these can be summarized as follows:

(1) The consumer's demand for a good or service is based upon his preferences and knowledge, subject to his income level and the price of the goods. In many cases there will be numerous sources of information to guide (and influence) his choice -- Consumer Reports, reputation of a manufacturer, advice from friends, prior experience, etc.;

(2) the consumer pays for the good directly; and

(3) the consumer selects the particular brand of the good, such as no-name cigarettes vs Craven 'A'.

On the supply side the conditions can be summarized as follows:

(4) There are many sources of supply.

Under these conditions, the resulting price, quality and quantity outcomes will maximize society's well-being, subject to a few, but important, caveats.[6]

In the drug industry, however, conditions (1) to (4) do not generally hold. We take each condition in turn and specify the corresponding condition in the drug industry. In doing so we pay particular attention to the role of the major actors in the drug delivery system; physician; manufacturer; pharmacist; provincial government; hospitals; private third-party insurance firms; and the consumer. In considering their role we scrutinize their part in determining: the choice of drug; the brand selected; and the price paid or charged to the individual or institution which pays for the drug. In this process, a number of terms will be introduced such as no substitution, generic, proper name, etc. A glossary of terms appears at the end of the paper.

2.2 The Demand Side

2.2.1 Consumer Demand

The consumer's demand for a drug is not based upon his own preferences or knowledge, except insofar as pain or other physical or mental inconvenience causes him to seek the advice of a physician. The advertising of prescription drugs to the general public is specifically prohibited.[7] Only a qualified medical practitioner (i.e. a physician or dentist) can write a prescription, defined as, "an order given by a practitioner directing that a stated amount of a drug be dispensed for the person named in the order" (Canada, Department of National Health and Welfare, 1980, p. 9). In other words, even if a

consumer was able to successfully self-diagnose his illness and select the correct medication, he would be unable to purchase the drug.[8] Hence, the physician acts as the agent for the consumer in deciding whether a drug is necessary or not and which drug is appropriate. These decisions are those of the physician and not the responsibility of any other health care professional. Because of this agency relationship, the importance of drug therapy to the consumers well-being and related factors, the demand for drugs is usually considered to be fairly insensitive to price changes.[9]

In terms of the brand finally dispensed by the pharmacist to the consumer[10] and the price charged, the physician's influence is primarily restricted to the former, but this carries with it implications for the price charged. In this respect it is important to distinguish between multisource drugs -- those for which more than one supplier exists -- and single source -- those for which there is only a single supplier. For example, only one brand of ranitidine, Zantac, is currently sold on the market, by Glaxo Laboratories, while for cimetidine, a leading high volume drug, there are four brands currently available, including that of the patentee.[11] An indicator of the importance of multisource drugs can be gained from the fact that in 1982 the Blue Cross plans across Canada estimated approximately 40 per cent of drug claims fell into this category,[12] while for Ontario, a separate estimate, put the percentage somewhat higher in 1983/84, between 40 and 60 per cent.[13] Our attention in this paper is primarily

directed at multisource drugs, which are subject to compulsory licensing. However, the findings are likely to be relevant to all multisource drugs.

In writing a prescription the physician has three choices: open; no substitution, and brand name. Although the information is somewhat fragmentary the percentages of all prescriptions falling into each category is 20 per cent, 1 per cent and 79 per cent, respectively.[14] If there is only one source of supply of a particular drug then it makes no difference which of these three is chosen -- only one brand can be dispensed and at a given price, usually that specified by the patentee. In the case of a no-substitution prescription for a multisource drug the pharmacist must dispense the brand which the physician writes on the prescription. In general, no-substitution prescriptions are written for the patentee brand, which is usually more expensive than the licensee brand. In the remaining two cases -- open and brand name -- the brand dispensed by the pharmacist depends upon the provincial rules concerning product selection. Table 1 provides a summary of such legislation for each province.

The impact of the physician on prices is thus indirect. To the extent no-substitution prescriptions are important the average price for a particular drug will be raised, sometimes dramatically. For example, in Saskatchewan, in the second half of 1984, the patentee brand of 300 mg. tablets of cimetidine retailed for 28.19 cents per tablet, while the lowest priced licensee brand, which

must be dispensed in all other cases apart from no-substitution prescriptions, retailed for 7.15 cents per tablet (Saskatchewan, Department of Health, 1984, p. 91 and below). We will return further to the issue of such prescriptions below.

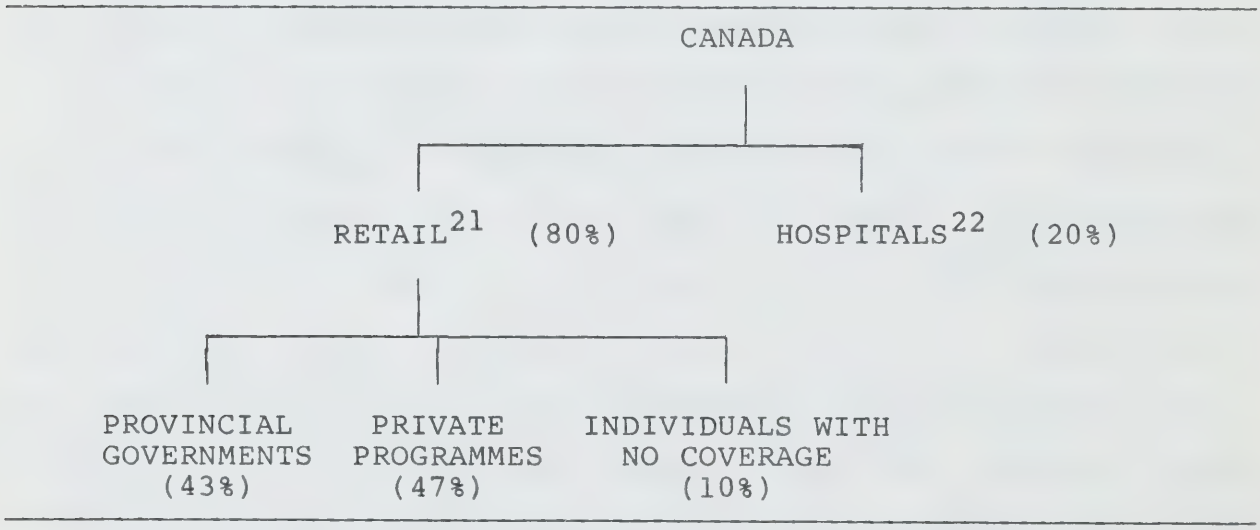
2.2.2 The Consumer Pays?

The second important attribute of the typical market is that the consumer pays for the commodity he consumes. In the case of drugs this has become progressively less the case throughout the 1970s. At the retail pharmacy level public payment for drugs through provincial drug reimbursement programmes has increased from less than five per cent in 1970, to 25.9 per cent in 1975 to 43.3 per cent in 1981.[15] Since drugs consumed in hospitals are also provided from the public purse, the percentage of all drugs purchased in Canada -- hospital and retail -- paid for by governments has increased from 25.3 in 1970, to 41.9 in 1975 to 54.0 in 1981.[16]

The non-public provision part of the market can be divided into those consumers that pay for their own drugs -- the cash-market -- and those consumers that are part of a private prepaid drug benefit programme, such as those offered by Rx Plus, Green Shield Prepaid Services and Blue Cross. It has been estimated that about 15 per cent of the Canadian population are without some sort of public or private scheme for payment of drugs,[17] which is consistent with a separate estimate for Ontario of 14 per cent for

1983/84.[18] Furthermore, in terms of drug sales this latter percentage is likely much lower, since the heavy users of drugs, particularly the over 65 years of age group, usually have their drugs provided by public plans.[19] Hence, for perhaps as little as a tenth of the sales of drugs in Canada is the person who takes the drug not part of some public or private drug programme.[20]

The net result of this brief discussion of who pays for drugs is that in large part it is not the consumer, but several distinct institutions, or group of institutions. In the early 1980s the situation could be characterised thus, where the percentages sum horizontally:



This categorization by purchaser is important because, as we shall see below, each institution frequently sets different rules concerning choice of brand and price to be paid. Furthermore there are frequently links between the rules made by one

institution with those of another, especially between the provincial and private reimbursement programmes. Hence, what we have is a series of sub-markets for drugs, both within and between provinces.

2.2.3 Choice of Brand

The third and final characteristic of the typical market is that once a consumer has decided that he would like to purchase a particular type of good -- a refrigerator, a case of beer, a pack of cigarettes -- then he makes the specific choice with respect to brand. In the drug industry this is not the case for several reasons: a large part of the drug bill is paid for by persons other than the consumer and such institutions make and operate under different rules concerning brand selection while in the cash-paying sector, restrictions on price advertising by pharmacists[23] and direct advertising to the consumer by drug firms, effectively prevent the consumer from making a choice among brands of the same drug based on either price or perceived quality differences.

The actual brand dispensed and the price paid by the consumer (or the institution ultimately responsible for paying) is subject to a fairly complex set of differing rules across Canada. We consider first the retail market and then the hospital market. Most of our attention will be confined to the public drug plans at the retail market level. Table 2 provides details of each of

these plans. This is done for several reasons: this sector, as noted above, is large and has been growing in importance throughout the 1970s and early 1980s. Furthermore, one of the sectors of the population covered by provincial plans -- those over 65 years of age -- are likely to increase their importance in the population[24] and are also heavy users of drugs;[25] and it would appear that the provincial reimbursement programmes have a substantial impact upon the private third-party programmes and the cash-market.[26] Hence, although we pay particular attention to the provincial sector, our findings will also be of relevance to the other sectors of the market. Furthermore, there is a limited examination of the interaction of the various segments of the retail market.

There are certain province-wide general rules concerning product selection and, indirect pricing. In some provinces, a further, usually more constrained, set of rules apply to drugs reimbursed under the provincial drug programmes. These rules do not apply, directly at least, to the private drug reimbursement programmes and the cash-paying sector. In Table 1 we present the general rules and in Table 3 the provincial government rules. The tables refer to 1983 with some reference to prior developments. As we shall see below a number of plans, particularly Quebec, have undergone quite radical transformations and data will therefore be presented which will not only discuss differences in 1983 but also through time.

Province-Wide General Rules. In all provinces, except Prince Edward Island, for which no product selection legislation has been implemented, product selection is permissive -- that is to say if the physician writes a brand-name prescription then the pharmacist may either dispense the brand-name written by the physician or product select a different brand. The brands of a drug which are considered equivalent, or to use the jargon of the legislation, interchangeable pharmaceutical products, appear in a formulary published by each province separately except Alberta and B.C. In these two provinces the pharmacist determines inter-changeability.[27] A provincial drug quality and therapeutics committee (or similar named body) composed of medical personnel from various fields decides which brands are interchangeable of the same drug.[28] The formulary is a semi-annual publication (usually January 1, July 1), and, as indicated in Table 3, sometimes list only high volume multisource drugs, in others a much wider range of multisource drugs and single source drugs.[29]

When a pharmacist decides to product select the legislation usually specifies that a lower-priced brand should be dispensed. Furthermore, although the legislation does not always specify it, lower-priced is usually with reference to the formulary, which lists prices for all brands. In the case of Ontario there is the added caveat that the pharmacist in product selecting cannot charge more than lowest cost brand in his inventory, while for Manitoba and Newfoundland, irrespective of the brand selected, the

pharmacist can charge no more than the lowest priced brand in the formulary.[30]

The third type of prescription is referred to as "open". In such instances the physician, instead of writing a particular brand name uses the generic or proper name. For example, rather than prescribing Apo-Cimetidine, Novo-Cimetidine, Peptol or Tagamet, the physician will prescribe, "cimetidine". The product selection legislation does not always deal specifically with the open prescription case, although it is clearly covered for Manitoba, Newfoundland and Ontario. This may reflect the fact that historically most physicians prescribed by brand name and the chief purpose of the legislation is to encourage selection at this level -- as noted above approximately 80 per cent of all prescriptions are still brand name. However, the legislation with respect to open prescriptions would appear to be reasonably straightforward. Under such circumstances, the physician has delegated to the pharmacist the decision as to brand choice. The terms mandatory or permissive are irrelevant. Hence Column 3 of Table 1 refers mainly to brand name prescriptions. The critical question is therefore what rules, with respect to cost, are specified in product selection legislation for open prescriptions. Two categories would appear to cover all the provinces having product selection legislation. First, the pharmacist is granted complete discretion to dispense the highest, lowest or some intermediate priced brand. Alberta, British Columbia, New Brunswick, Quebec and Saskatchewan would appear to fall into this category. The second rule specifies that the pharmacist can

charge no more than either the lowest priced brand in his inventory (Ontario) or in the formulary (Manitoba and Newfoundland) no matter which brand is dispensed. While these are the general rules as to product selection and pricing we now turn to that subset for which the provincial government reimburses the pharmacist.

Provincial Drug Reimbursement Plan Rules. Details of the methods by which provincial drug reimbursement programmes establish the cost of a drug for the purposes of payment to the pharmacist, either directly or indirectly, and whether product selection is mandatory or not under the programme are presented in Table 3. In Table 2 details of the coverage of the provincial plans in terms of population covered, percentage of provincial drugs dispensed accounted for by the government plan, and details of any patient co-payment are presented. In most provinces those on welfare and over 65 years of age receive some sort of government assistance, with other groups occasionally being included, such that in B.C., Manitoba and Saskatchewan the whole population is covered by the provincial plan, but all three have co-payment features. Hence the importance of the provincial government drug reimbursement rules are likely to vary considerably across Canada.

The province-wide general product selection rules presented in Table 1 do not differ from these in Table 3 referring to the provincial drug reimbursement plan rules, except for

Saskatchewan.[31] For this province product selection is mandatory on those drugs subject to Standing Offer Contracts (SOC), which consist of high selling multisource drugs purchased by tender. Since, as detailed in Table 2, the Saskatchewan drug plan covers the whole of the province's population, mandatory should replace permissive product selection, at least for the high volume multisource drugs.

A number of provinces, although having only permissive product selection legislation have what might be termed mandatory price selection: no matter which brand is dispensed the provincial government will only reimburse up to a certain price, irrespective of the brand dispensed -- sometimes referred to as Maximum Allowable Cost or MAC.[32] In the case of Ontario, Newfoundland, Manitoba and Saskatchewan the MAC is the lowest-priced brand among a group of interchangeable pharmaceutical products, while for Quebec the median priced brand is the MAC. However, in Quebec from July 1, 1983 a single price is specified for six high volume multisource drugs in the formulary[33] -- if the pharmacist purchases the drug for less than this price then the province will only reimburse this lower price. For SOC drugs in Saskatchewan the combination of mandatory product selection and mandatory price selection means that the lowest priced brand must be dispensed at the price in the formulary. As noted above, mandatory price selection rules apply to all sections of the provincial market for Newfoundland and Manitoba, while for Quebec and Ontario such rules apply only to the province's drug plan. Since the Saskatchewan

plan applies to the entire population, its rules are also province wide. Finally, the Alberta, British Columbia, New Brunswick and Nova Scotia drug reimbursement plans have no added incentive or rules to encourage the dispensing of lower-priced brands.

In sum then, in contrast to the typical market, brand choice is not the prerogative of the consumer, but rather the physician and pharmacist, subject to certain legislative and provincial government drug plan rules and regulations. Without government intervention it would appear brand-name prescriptions are typically written and dispensed, usually for the patentee's brand. Permissive product selection legislation permits but does not compel or provide much incentive for product selection. Hence, in varying degrees government, either for the entire province or just its own drug plan, specifies the brand to be selected or that the pharmacist will not be reimbursed above a certain, usually low price, thus encouraging the dispensing of the lower-priced licensed brands.

2.3 The Supply Side

The supply side characteristic of the typical market that we identified above was that there were many suppliers of the product. In the drug industry several suppliers of a drug is not an entirely accurate reflection of supply conditions in most OECD countries today and for Canada up to 1969.[34] Rather a single

supplier usually existed for individual drugs or chemical entities. Such a situation was a reflection of several factors: patent protection; heavy advertising to the physician and pharmacist which established the brand-name; and expensive health and safety regulatory procedures which were and are required to be fulfilled before a drug can be marketed to the public. This does not mean, of course, that no competition exists in the industry, but rather it takes the form of product innovation, rather than price competition amongst a group of homogeneous or slightly differentiated goods.

In Canada, the introduction of section 41(4) in 1969 and the associated provincial product selection legislation and drug reimbursement programms dramatically changed this somewhat stylised picture of supply conditions. The three entry barriers -- patent protection, advertising, and regulatory expense -- cited above were all severely attenuated by these policies in Canada. While product innovation remains important, particularly in a world context, price competition for drugs which would, in most of the OECD countries still be impossible, has increasingly became the norm in Canada during the 1970s and 1980s.

The introduction of section 41(4) allowed those firms holding licenses, which were issued almost as of right and usually within a year or so of their initial application, to compete directly, upon the payment of a 4 per cent royalty fee based on the licensee's price, with the patentee.[35] These licenses were

usually issued to import and manufacture, the licensee typically importing bulk active ingredient, with final dosage preparation taking place in Canada.[36]

Over the period 1970 to 1983, as shown in Table 4, 181 compulsory patent licenses[37] have been taken out against 58 drugs by approximately 30 firms or licensees. As of 1983 of the 181 licenses, only 66 were being worked, in that the licensee had its brand of the licensed drug on the market. Nevertheless, of the top 50 selling drugs in Canada in January 1983, 21 faced competition from at least one licensee.[38] There are a number of reasons which explain the shortfall between licenses issued and licenses worked: the licensee may have marketed the drug prior to 1983 but subsequently gone bankrupt, merged or withdrawn from the drug industry;[39] in a small number of cases the licensee has been interested primarily in manufacturing the bulk active ingredient in Canada and this may not have resulted in the licensee preparing the drug in form suitable for the consumer -- final dosage preparation;[40] and the licensee is still in the process of bringing the licensed drug to market, due to delays in completing drug regulatory clearance procedures or obtaining suitable sources of the drug raw material.[41] Table 4 shows that in terms of both licenses granted and, particularly, worked four firms dominated the licensee sector - ICN, Apotex, Horner and Novopharm -- accounting for 47 per cent of all licenses granted and 78.9 per cent of licenses worked as of 1983. In terms of the sales of all

licensees, these four firms accounted for $105 million of the total of $125 million in 1982.[42]

The second barrier to the establishment of a successful product competing with the patentee's product is the brand or product differentiation built up by the originator.[43] However, provincial government product selection legislation certifying interchangeability of licensee and patentee brand, as well as the introduction of rules encouraging and, in some cases, compelling the selection of the lower-priced licensee brand, has gone a considerable way to open the market for price competition, thus providing the licensee the opportunity to use about the only competitive advantage he possesses over the patentee.

The third and final barrier -- expensive testing to meet health and safety standards -- is not as onerous for the licensee as the patentee or originator. The latter may have to spend millions of dollars to secure regulatory approval, but the tests the licensee must complete cost only thousands of dollars.[44] Nor, it should be added, does the licensee have to bear the considerable costs of discovering and testing a drug prior to seeking regulatory approval.[45] In other words, the licensee is not usually required to replicate the tests nor the research of the patentee, but only provide some bioequivalence and purity tests.

Hence, on the supply side, in contrast to the demand side, we have conditions which approach that of a typical market, because of government intervention.

2.4 Conclusions

The market for drugs does not conform to the typical view as to what constitutes an efficient workably competitive market. Few, if any, of the conditions on the demand side are fulfilled, while on the supply side only with government intervention have the conditions of fewness been eliminated. Hence, it is difficult to judge how well the market is performing, given the large role of government and various restrictions on advertising. Indeed, the role of government is large precisely because the market is not in an important sense workably competitive and the government has decided or felt it is not possible to make the market workably competitive by, for example, permitting advertising by pharmacists. The remainder of the paper essentially examines the impact of government and the degree to which price reductions at the manufacturing level are passed-on to the consumer. In effect this becomes our measure of performance of the drug industry and the standard against which to measure government success.

III DETERMINANTS OF THE PRICE LEVEL

3.1 Introduction

In this section we attempt to specify those factors which are likely to determine the degree to which price reductions occasioned by compulsory licensing at the level of the manufacturer will be passed on to the consumer. In addition to specifying these factors we provide some preliminary findings and evidence related to each factor for a sample of drugs and prices. Furthermore, we attempt, taking all these factors together and the available evidence, to specify, *a priori* which government reimbursement schemes will be most successful in realising the savings due to compulsory licensing. In section IV we quantify the extent to which price reductions are realized and hence are able to test the predictions made in this section.

Our attention is confined to all provinces, except Alberta and Manitoba, for which reliable data was not readily available. Reference to Tables 1 to 3 suggests that there is enough variation in the remaining provinces for us to be able to draw inferences about the influence of various factors such as product selection legislation, that may affect drug prices. Furthermore, several of the more important features of the Alberta -- permissive product selection -- and Manitoba -- mandatory price selection -- are present in several of the other provinces. In 1984 Alberta and

Manitoba accounted for 11.8 per cent of the Canadian drug market.[46]

In order to aid our discussion a sample of seven multisource licensed drugs that would permit inferences to be drawn about drug prices and compulsory licensing is used. This sample was already available.[47] It had certain characteristics: all were high volume -- Canada-wide sales of $2 million or more in 1981 and/or 1982; came from a variety of therapeutic categories; and were originally introduced, by the patentee, at various points over the period from the 1960s to the present. The seven drugs accounted for 29 of the 181 (16.0 per cent) licenses issued between 1970 and 1983, and 18 of the 65 (27.7 per cent) that were being worked in 1983. Although our core sample is restricted to seven drugs, with the data usually referring to 1983 and/or early 1984, in a number of cases data was available for an earlier period and/or a wider sample of drugs for a particular province. In such instances, where appropriate, data is presented for the larger sample.

Table 5 provides the identity of the sample of drugs, for which attention is confined to the most popular dosage form and strength. Most of the table is self explanatory, except column 6. There may be a difference between the identity of the licensees and the non-patentee firms selling a drug for which the patent is still extant. In column 6 of the table the number of licensees marketing the drug is not in parenthesis, while the total number of non-patentee brands on the market is presented in the parenthesis. For example, Drug Trading Co. Ltd. is listed in the

Ontario formulary as selling propranolol, but there is no record of this firm obtaining a license from the Commissioner of Patents. This reflects the fact that in such instances a licensee will prepare the final dosage form and strength of the tablet or capsule for such non-licensee non-patentee firms.[48] Hence the number of non-patentee brands may exceed the number of licensees. This is particularly the case in Ontario and Quebec.

3.2 The Determinants

3.2.1 Setting the Stage

In order to be able to evaluate the factors which will influence the mean price level of a licensed drug we need some model, or picture, if you will, of what the drug delivery system was prior to the introduction of section 41(4) and associated provincial government policies and programmes. This benchmark or initial set of conditions can then be used as our point of departure to predict the influence of public policy.

In the 1960s following a series of government inquiries into the drug industry,[49] the major characteristics of the industry, for our purposes, could be set forth thus:

(1) physicians typically prescribed by brand-name where the patentee brand was selected. This situation reflected several factors: considerable advertising of the patentee which placed much emphasis on the brand-name which is shorter and easier to remember than the

proper or generic name; brand loyalty to the patentee because of its innovative capabilities and other services it provided the physician; a concern over the quality of the generic product; and the physician not paying for the drug.

(2) the pharmacist dispenses the brand-name prescription. This situation reflected several factors: no product selection legislation in Canada existed in the 1960s, except for Alberta, introduced in 1962; a pricing system for a prescription based on a mark-up on cost, with the patentee brand usually being the higher priced; and all the same factors cited above for the physician.

(3) the consumer was able to exercise little if any influence over price or brand choice because of the factors mentioned in section 2.2 above.

Under such conditions the patentee will have a substantial degree of latitude in setting price, being constrained mainly by the relative prices of other drug products treating the same conditions.[50]

Throughout the 1970s and 1980s the federal and provincial governments have introduced policies to encourage the prescribing and dispensing of lower-priced licensee products. Many of these policies have been mentioned above and include: section 41(4) of the Patent Act; certifying interchangeable to remove the quality issue; pricing a prescription on the basis of a dispensing fee and ingredient cost to remove the incentive to dispense higher-priced brands; product selection and price selection rules to encourage/ ensure lower-priced brands dispensed; information and education programmes aimed at encouraging the prescribing and dispensing of

lower-priced brands; but no steps taken to allow the consumer to play a greater role. In other words, the physician and pharmacist have been the main targets of government. We now turn to the influence of these and other factors on the mean price level.

3.2.2 Interchangeability and Formulary Listings

The mean or average price of a particular multisource dosage form is likely to be lowered if the formulary lists the drugs as interchangeable for at least two reasons. First, to the extent that the formulary serves as a drug benefit list, as is the case in Ontario, Quebec and Saskatchewan,[51] then the province will only reimburse for those brands and drugs listed. Hence, if a particular drug or brand is not listed then the provincial reimbursement plan will not reimburse the pharmacist if that brand is dispensed. Second, interchangeability gives the licensee the opportunity to compete with the patentee on a price basis, with the success of the licensee depending upon the pricing and product selection rules of the province. Hence, the listing in a formulary is likely to be a very important, indeed perhaps necessary step, in creating price competition in the marketplace. In a recent court case concerning Ontario the judge was moved to remark, "A manufacturer of prescription drugs cannot market its product effectively unless it is in the [Ontario] formulary."[52] This is supported by statements in several of the briefs to the Commission.[53] Furthermore the sooner a province is able to list a

drug as interchangeable the sooner the benefits of licensee competition will be available.

Table 6 shows us that some provinces -- New Brunswick and Newfoundland -- do not list as interchangeable three to four of the seven drugs in our sample. This provides an opportunity to test for the importance of formulary listing. In Table 7 we present our results. In the first panel we compare Newfoundland and Saskatchewan -- both of which have strong selection/substitution rules -- and New Brunswick and Nova Scotia -- both of which have weak selection/substitution rules. In each case we compare the average licensee market share for those drugs which are (are not) interchangeable for Newfoundland and New Brunswick with the corresponding market share in Saskatchewan and Nova Scotia where all seven of the drugs are interchangeable. The results indicate that formulary listing has a marked positive effect on licensee market share. For example, the mean licensee market share of the three drugs not listed as interchangeable in Newfoundland was 9.7 per cent, whereas in Saskatchewan, where all three were interchangeable, licensees accounted, on average, for 59.2 per cent of the market. Hence to the extent licensees charge lower prices than patentees, formulary listing will lead to lower prices.

In Table 6 we tabulate for each drug and province in our sample when the drug was first listed in the formulary (i.e., always the patentee brand but sometimes with licensee brand simultaneously,

usually for the Maritime provinces where formularies were introduced later than Ontario and Quebec), the number of brands currently listed as interchangeable in January and July 1983 and January 1984, the date at which the patentee, first, second, and third licensee brands were listed as interchangeable.

The table leads to a number of conclusions. First, New Brunswick and Newfoundland do not list some multisource drugs as interchangeable at all. For example, Table 6 shows that indomethacin 25 mg. caps are not included in the New Brunswick or Newfoundland formularies. Second, some provinces lag considerably in listing the first licensee brand as interchangeable. In particular Saskatchewan, Ontario and Quebec usually list the patentee brand, first and subsequent licensee brands at about the same time, while the Maritimes lag considerably reflecting in part, no doubt, the fact that the Maritime provinces' formularies were introduced several years after those of Quebec, Ontario and Saskatchewan. Nevertheless, by January/July 1983 Nova Scotia, Newfoundland and New Brunswick had the primary licensee brands (i.e., those of the leading licensees identified in Table 4 listed). Third, Ontario and, particularly, Quebec frequently had a greater number of brands listed than Saskatchewan and the Maritimes. This reflects the fact in Ontario and Quebec smaller firms purchased licensed drugs from the licensees and retail them under their own brand. In Table 6 such firms are referred to as licensees and this convention is followed in subsequent tabulations, unless otherwise indicated.

We consider the question of the number of competitors -- brands listed as interchangeable in the provincial formulary -- further in section 3.2.4 below. In this section our main concern is whether one can rank the six provinces in our sample on their willingness to list drugs as interchangeable, having shown that interchangeability clearly has a major influence on the market share of the licensees and, hence, on the mean price level. In terms of a broad categorization Ontario, Quebec, Nova Scotia, and Saskatchewan would be in one group and Newfoundland and New Brunswick in another. The question of British Columbia, which has no formulary, is deferred until section 3.3.

3.2.3 Price and Product Selection Rules

We now move to the influence of price and product selection rules -- that is rules which guide the pharmacist in selecting the brand to be dispensed and/or the price. We can categorize the provinces in our studies in three different situations, which we present in Table 8. In terms of ranking the probable impact of each of rules or prices we would expect, other things equal, prices to be lowest in Saskatchewan followed by Ontario, Quebec and Newfoundland, with British Columbia, Nova Scotia, and New Brunswick having the highest prices. Our reasoning for this is as follows: we would expect the price to be lower the more competitive the market and the higher the probability that the lowest price supplier would command a substantial share of the market. The case of Saskatchewan falls at one end of the spectrum

where a tendering basis picks the lowest price and the supplier, while in British Columbia, New Brunswick, and Nova Scotia substitution is permissive and, apart from a smaller inventory, there is little incentive to substitute and depart from the status quo; the other category is in an intermediate position because either the lowest priced supplier, in Ontario and Newfoundland, or the median priced supplier, in Quebec,[54] only sets the ceiling and does not necessarily receive a substantial share of the market. Nevertheless, in Quebec, with median pricing, the price may be above Ontario and Newfoundland. However, in terms of the broad rankings this is likely to be relatively unimportant. Thus our ranking is as follows, from lowest price to highest price:

1. Saskatchewan	2. Quebec Ontario Newfoundland	3. British Columbia Nova Scotia New Brunswick

The predictions with respect to mean price levels are likely to apply, mutatis mutandis, to the market share of the licensee. We therefore present in Tables 9 to 11 information relating to the market share of the licensees. In each case we present a quantity (e.g., number of capsules or tablets, number of prescriptions or number of claims) and price (e.g., sales, drug cost) share to capture any differences in price between licensees and patentee. (Unfortunately for Table 11 we had only a quantity based measure.) If there are no price differences between patentee and licensee prices then the quantity and price market shares will be the same, but if, as is more likely, the patentee is able to command a higher price for at least part of his output, then the licensee

market share will be higher measured in quantity than price terms.

In Table 9 we present, for the seven drugs and the dosage form and strength selected, the average licensee market, by province, usually in 1983 or some sub-period thereof. In Table 10 we present similar data but for a different sample of drugs, for a more limited sample of markets, but for a longer time period - the mid-1970s to 1983. The principal difference between Tables 9 and 10 is that the former refers mostly to licensed drugs for which the licensee first marketed a brand in the 1980s, whereas Table 10 refers to licensed drugs which were first sold by a licensee in the 1970s. Only one drug is common to both Tables 9 and 10 -- methyldopa 250 mg. tabs. The final table, Table 11, refers to a sample of seven drugs, for the province of Quebec, for the last three months of 1981 and the first three of 1982. The importance of this period is that prior to 1982 the Quebec drug reimbursement programme had permissive product selection legislation with the drug programme paying the price of the brand as submitted by the manufacturer. As of January 1, 1982 the system changed and median pricing was introduced by the provincial government programme, with the remainder of the market still subject to the pre-1982 rules -- permissive product selection, no pricing rules. However, Table 11 refers to the whole of Quebec not just the government reimbursement sector of the market. Hence Tables 9 to 11 provide a rich array of data with which to compare our predictions about

the influence of product and price selection rules on licensee market share.

The a priori ranking of licensee market share, on the basis of price/production selection rules, is broadly consistent with the results in Table 9, for the seven drug, seven province sample. In particular, in those provinces with weak price/product selection rules -- New Brunswick, Nova Scotia, and British Columbia -- the licensees account for a much smaller percentage of the market -- whether measured in terms of quantity or sales -- than where stronger rules exist -- Ontario, Quebec, Saskatchewan, and Newfoundland. However, within each of these two groups there is some variation in the market share of the licensees. Since the a priori rankings only distinguished among those four provinces with strong price/product selection rules we confine further discussion to them. However, it should be noted that in British Columbia the licensee market share is much greater than either New Brunswick or Nova Scotia. This may be due, in part at least, to actual acquisition pricing, a subject which will be discussed in section 3.2.5 below.

Among the four provinces with strong price/product selection rules we expected, on the basis of our earlier discussion, the licensee market share to be highest in Saskatchewan, followed by Ontario, Newfoundland, and Quebec, all ranked about equally, but with the possibility that Quebec would be the market where the licensees would be least successful. The evidence in Tables 9 and

10 is not consistent with these predictions. In particular Ontario is consistently ranked first, with the licensees taking approximately 80 per cent of the market, no matter how measured. Saskatchewan and Quebec follow but in no consistent rankings across the two tables, followed by Newfoundland. We now attempt to explain some of these deviations from our predicted rankings.

On the basis of the earlier discussion the licensee market share in Saskatchewan should be 100 per cent. However, as Tables 9 and 10 show the licensee market share is substantially below 100 per cent. Furthermore, there is a large discrepancy between the licensee market share for Saskatchewan measured in terms of quantity and sales. These findings can be explained by the physicians in Saskatchewan writing no-substitution prescriptions for the patentee brand, with the province paying the patentee's price and not the much lower price of the firm which was awarded the SOC for those prescriptions.[55] In other words, the patentee has a large non-trivial section of the market where it can charge a price similar to that which would prevail had compulsory licensing and associated provincial government programmes not been introduced. Hence the discrepancy between the sales and quantity market share of licensees. These differences and the importance of no-substitution prescriptions have been commented upon earlier (Gorecki, 1981, pp. 142-147) and by the Saskatchewan Prescription Drug Plan (1984) in its brief to the Commission.[56]

It might be noted, parenthetically, that the price/product selection rules that apply to Saskatchewan also apply to Hospital Purchasing Inc., (HPI) which purchases by annual tender drugs for a large group of hospitals in the Toronto area. (Gorecki, 1981, pp. 129-131). For the ten drugs in Table 10 the licensees held 90 per cent of the HPI market by 1984/85 (i.e., were awarded nine of the ten contracts), while for the seven drugs in Table 9 the licensees held 100 per cent of the HPI market in both 1983/84 and 1984/85 (i.e., were awarded all seven contracts). Furthermore, an examination of the bids revealed that frequently the patentee's price was so much higher than the licensee's as to suggest the patentee was not a serious contender. To the extent the hospital market operates like HPI then the licensees will clearly dominate because of the very strong product selection rules.

The rules for Ontario and Newfoundland concerning price/product selection are very similar and hence it was predicted above that the licensee market share should be similar in these two provinces, other things equal. However, in Table 9 for Newfoundland the licensee market share is much lower than Ontario. This is largely a reflection, however, of the fact that four of the seven drugs in our core sample were not interchangeable in Newfoundland. Reference to Table 7 shows that considering only the three drugs which were interchangeable in Newfoundland with the same sample in Saskatchewan, that the licensee market share was, on average, much higher in Newfoundland (76.0 per cent vs 57.2 per cent). Unfortunately comparable data for Ontario was unavailable

to the author, but if the market share of the licensees gained in the three drugs that were interchangeable in Newfoundland were replicated for the other four drugs,[57] not certified as interchangeable in that province, then Ontario and Newfoundland could be ranked pretty close measured in terms of licensee market share. Hence it would appear that if Newfoundland had had all seven drugs listed as interchangeable in the provincial formulary, the licensee market share in Newfoundland would have been above that of Saskatchewan and close to that of Ontario.

Licensee success in gaining market share is less for the newer drugs in Table 9 than the older drugs in Table 10, for the three provinces common to both tables -- Quebec, Ontario and Saskatchewan. Hence there would appear to be stronger brand loyalty amongst pharmacists and physicians to the patentee brand of newer drugs compared with older drugs. The difference between the mean market shares of the licensees in the two tables is particulary noticeable for Quebec, where an additional factor may have been that patentees successfully reduced their prices to compete with licensee brands.[58]

Most of the discussion on licensee market share so far has focussed on interprovincial differences in such shares and then related such differences to price/product selection rules. The only province for which time series data is available that covers an important change in the price/product selection rules is Quebec. As noted earlier in this section this occurred at the

beginning of 1982. Relevant data is provided in Tables 10 and 11. In both instances we see substantial increases in the market share of the licensee in response to the change from fairly lax price/product selection rules to median pricing.

In sum, our findings on licensee market share suggest that price/product selection rules can have a profound impact on the success of licensees in penetrating markets formerly held exclusively by patentees. While we have not been particularly successful at predicting licensee market share between provinces with similar but not exactly the same price/product selection rules, the broad prediction that in markets with strong price/product selection rules licensees gain considerable market share compared with provinces with weak rules is borne out by the results of Tables 9 to 11.

3.2.4 Number of Competitors

The number of competitors -- brands listed as interchangeable -- is also likely to be an important factor determining the price of drugs. In particular, the greater the number of brands, other things equal, the more competitive the market and the lower the price. Furthermore, one might expect a non-linearity in the relationship -- once a critical number is reached further price declines will be much lower, if any at all.

We assume that prior to the entry of the first licensee the single source patentee supplier follows a policy of short run profit maximization not taking into account the threat of entry.[59] Subsequent to the entry of licensee competition we assume that the patentee will maintain a high price in those markets where no substitution is important and gradually reduce its price in other markets.[60] When the first entrant appears it can charge slightly below the patentee price and, if the market were perfectly competitive and reactions instantaneous, capture 100 per cent of the market. However, since reactions are less than instantaneous, licensee progress will vary depending upon the cost and pricing rules, as discussed in the previous section. Nevertheless as new entrants appear, usually charging a lower price than existed prior to entry, the price structure will tend to shift downward. At some critical number of licensees, competition will be confined mainly to the licensee brands with the patentee standing back from the fray.

One patentee who has had ample opportunity to observe licensee pricing patterns in Hoffman-La Roche Limited. Four of its major products since the 1960s have experienced licensee competition -- chlordiazepoxide (Librium), diazepam (Valium), trimethoprim/sulfamethoxazole (Bactrim) and flurazepam (Dalmane), apparently with substantial effect on the firm's sales.[61] In Roche's view the pricing policy of licensees can be summarized as follows:

> In the early 1970's, generic companies normally waited for the sales of a given product to reach an attractive sales level before applying for licences. However, it soon became apparent to them that their profits were

> substantially reduced when they had to compete among themselves for a share of the market. The generic companies recognized that the company which could be the first licensee, only having to compete with the originator with its much higher cost structure, could achieve significant sales and profits until such time as the second and subsequent generics arrived upon the scene and forced it to lower its prices. Accordingly, the time lag from introduction by the originator to the application for compulsory licence by a generic company has shortened dramatically, and today, an application for licence is often made relatively soon after a potential "winner" is introduced in Canada by the originator. (Hoffman-La Roche Limited, 1984a, pp. 8-9).

In its supplementary brief to the Commission a similar view is expressed.[62]

Table 6 shows for our sample of seven drugs for 1983, the year for which the price data we have is available, the number of licensee brands listed in each provincial formulary. The table shows that Quebec has as many or more brands than any other province, followed by Ontario, with Saskatchewan and Nova Scotia ranked about equally. Next, New Brunswick and Newfoundland both of which have several zeros, bring up the rear. However, the difference in the number is not usually that great between provinces for an individual drug; in those instances where it is (particularly methydopa 250 mg. tabs, flurazepam 30 mg. caps, and allopurinol 100 mg. tabs) even the lowest ranked province has two or three licensee brands. This may be all that is required to yield the benefits of compulsory licensees.[63] Hence, at a broad brush level we would rank Quebec, Ontario, Saskatchewan, and Nova Scotia in one group, followed by New Brunswick and Newfoundland in

another. The question of the number of competitors in British Columbia is deferred for consideration in section 3.3.

3.2.5 Determination of Cost

Each province has a different method of determining the prices at which it will reimburse the pharmacist for the drug component of a prescription. In Table 3 these are summarized in the column titled, "Drug Cost Definition for Reimbursement". The cost determination procedures can be divided into roughly four major categories, which together with the province(s) in each category, are as follows: actual acquisition cost to the pharmacist -- British Columbia; a tendering or SOC system -- Saskatchewan;[64] the cost to the pharmacist with an attempt to take into account the savings due to purchasing larger package sizes -- Ontario,[65] Quebec,[66] Nova Scotia and Newfoundland;[67] and the cost to the pharmacist of the smallest package size -- New Brunswick. One would expect that prices based upon manufacturers and wholesalers price lists to be higher than the actual acquisition or transaction cost of the pharmacist. Indeed, at least one of the provincial formularies acknowledges this, by saying the difference between the two prices can be considered an efficiency creating device for pharmacists to purchase in bulk.[68] Hence, other things equal, prices should be lower in British Columbia and Saskatchewan than Ontario, Quebec, Nova Scotia, and Newfoundland, with New Brunswick ranked last because it bases prices upon the smallest package size using list prices. The tendering system which

operates in Saskatchewan should ensure lower prices than British Columbia even if the tenders are based on the smallest (usually 100's) package size. Hence we rank the provinces from lowest to highest price as follows: Saskatchewan; British Columbia; Ontario, Quebec, Nova Scotia, and Newfoundland; and, finally, New Brunswick.

3.3 Conclusion

In the previous sections of the paper we identified four factors -- interchangeability, price/product selection rules, number of competitors, determination of cost -- which were thought, *a priori*, to be the major determinants of the mean price level paid by seven provincial drug reimbursement programmes for seven drugs.[69] We considered each factor separately and ranked its impact on each provincial drug reimbursement programme's mean price level. In doing so we attempted, as far as possible, to group provinces together where a given factor could be expected to have the same impact. Our objective is, via these rankings of individual factors, to identify the province which will likely pay the lowest through highest mean price. The orderings are ordinal and we do not attempt to rank the importance of the four factors, although interchangeability and number of competitors, in practice, work out to be very similar.

In Table 12 the impact of each factor is ranked consistent with our earlier discussion. The higher the rank the greater the

expected impact of that factor in lowering the mean price paid by the province for the sample of drugs. In our earlier discussion of interchangeability and number of competitors we excluded British Columbia because of this province did not have a formulary. Hence we place a question mark in Table 12 for British Columbia for these two factors. However, an examination of the number of firms selling in British Columbia places it with numbers comparable to the other provinces.[70] As a result we insert the ranks in brackets.

In terms of overall rankings our results permit us to predict unambiguously the province with the lowest mean price -- Saskatchewan -- and highest mean price -- New Brunswick. Although not discussed extensively above the tendering system of HPI would see it ranked joint first with Saskatchewan. Ontario and Quebec rank the same on all four factors, but rank equal to or above, on at least one factor, Nova Scotia and Newfoundland. We find it difficult to separate these last two provinces and hence rank them, overall, the same. The difficulty is British Columbia -- where interchangeability is weak, the price/product selection rules lax, but prices are based upon actual acquisition cost -- compared with Ontario and Quebec. Given our earlier findings that interchangeability is very important as is the price/product selection rules in promoting licensee market shares, we decided to place British Columbia behind Ontario and Quebec, but with Nova Scotia and Newfoundland. We now turn to the use of these

predictions in evaluating the savings due to compulsory licensing and associated provincial measures.

IV THE SAVINGS

4.1 Introduction

This section has two major objectives. In section 4.2 we measure and compare the actual and potential maximum savings due to compulsory licensing and associated provincial government programmes for our core sample of seven drugs and seven provinces.

An important issue concerns the explanatory factors, which we have discussed at some length in section III, that account for the inter, as well as intra, provincial variation in the degree to which potential savings are actually realized. This issue we address in section 4.3, with the results providing, potentially at least, some guide to future policy. In section 4.4 we discuss some potentially important qualifications to our work.

4.2 Measuring the Savings

The approach adopted to measuring the savings can be illustrated with reference to Figure 1: P_PACP_L represents the potential or maximum dollar savings that government programmes can realize; P_PABP_A the actual or realized savings due to these programmes; and the difference, P_ABCP_L, the savings that remain to be captured. In Appendix B we present a detailed discussion of the derivation

of P_P, P_L, P_A, and Q_A and the assumptions made about the elasticity of supply and demand.[71]

We define three indices which attempt to measure various facets of the success of governemnt policy in the drug industry. The first index measures the potential savings (as defined above) due to compulsory licensing compared to the total expenditure on the licensed drug had compulsory licensing not been introduced (i.e., $P_P Q_A$). Hence, this measure can be defined as follows:

$$\text{POTSAV} = \left[(P_P - P_L)\cdot Q_A\right] \;/\; P_P \cdot Q_A = 1 - \frac{P_L}{P_P}$$

where all the terms are defined in Figure 1. This index will vary between 0 and 1. In the former case there are no savings because of compulsory licensing and associated government programmes since $P_L = P_P$. In the latter case, where POTSAV = 1 then $P_L = 0$ -- in other words, the drug is being given away free by the licensee. Hence the potential savings to be realized by government programmes is inversely related to POTSAV.

The next two indices attempt to measure the degree to which the potential dollar savings -- $P_P ACP_L$ in Figure 1 -- are realized by government policy. Hence we define:

$$\text{ACTSAV} = \left[(P_P - P_A)\cdot Q_A\right] \;/\; \left[P_P - P_L)\cdot Q_A\right] = (P_P - P_A)/(P_P - P_L)$$

where all the terms are defined in Figure 1. This index will vary from 1, where $P_A = P_L$, indicating that the actual price paid by the government reimbursement programme is the lowest obtainable, to 0, where $P_A = P_P$, indicating that the government is reimbursing at the patentee price. Hence ACTSAV varies directly with the degree to which government policy has been successful in capturing the potential benefits of compulsory licensing.

The final index, UNSAV, or uncaptured savings, is an attempt to measure the savings that it is still possible to capture, in relation to potential dollar savings, as defined above. Hence we define:

$$UNSAV = \left[(P_A - P_L)\cdot Q_A\right] / \left[(P_P - P_L)\cdot Q_A\right] = (P_A - P_L)/(P_P - P_L)$$

which is also equal to 1 - ACTSAV, where all the terms are defined in Figure 1. UNSAV is the complement of ACTSAV, hence it will vary directly with the saving that remains to be captured by the efforts of government. In view of the relationship between UNSAV and ACTSAV most of the exposition will concentrate upon ACTSAV.

In Appendix B we discuss at some length the measurement of P_L, P_A, and P_P, the problems involved and the sensitivity of the estimates. Suffice to say here that P_P is chosen by identifying a market(s) in Canada where compulsory licensing and associated provincial governments are likely to have had little impact on the

mean price paid by the provincial government for a multisource drug. The market selected was the no-substitution market in Saskatchewan. The patentee prices recorded in this market were not significantly different from those either in New Brunswick or the United States. P_L, the price which would be charged if the drug market for a particular multisource drug were perfectly competitive, was approximated by the actual prices charged by the licensees, two of whom provided data, independently, on their actual prices. The two sets of prices were not significantly different. Hence, P_L is the licensee actual selling price, P_P is the patentee price in the no-subsitution market in Saskatchewan and P_A is the actual price that the respective provincial government pays for a given drug.

We present in Table 13 values of the three indices estimated for the seven drugs in our sample for the seven provinces we consider. As will be readily apparent, since POTSAV is defined in terms of P_L and P_P, which remain invariate with respect to the individual provinces, POTSAV is the same for all provinces, indeed for the whole of Canada. The two remaining indices will vary by province, because P_A in general is not the same for each drug for each province. Hence the discussion in section III concentrated upon the likely ranking by province of P_A.

Table 13 shows that there are substantial potential gains to be made from a well designed provincial drug reimbursment programme, given the existence of compulsory licensing. On average, provin-

cial governments should be able to reduce their drug bills for the seven multisource drugs (POTSAV) by 65 per cent, compared with the expenditure that would be incurred had compulsory licensing not been introduced. This is consistent with earlier work which also suggested quite striking savings were available.[72] However, the degree to which the potential savings are actually captured by the provinces (ACTSAV) differs considerably from practically zero for New Brunswick to about 50 per cent for British Columbia and Saskatchewan. Although not shown, for the year 1983/84 HPI recorded a value of 1.00 -- in other words, it gained all of the potential benefits of compulsory licensing. Furthermore, in all instances, except HPI, there are still significant further reductions to be obtained (UNSAV). We now turn to the discussion of UNSAV and ACTSAV in relation to our analyses in section III of the determinants of P_A.

4.3 Matching Rankings

In section III of the paper we ranked the seven provinces in our sample, from lowest to highest, by its predicted value of P_A across the seven drugs in our sample. The rankings are presented in Table 12. In section 4.2 we designed two measures, ACTSAV and UNSAV (i.e., 1 - ACTSAV), to gauge the degree to which potential savings due to compulsory licensing have been realized by the various provincial drug reimbursement programmes. An inspection of the definition of ACTSAV and UNSAV makes clear the predicted rankings of P_A in Table 12, if correct, should match the rankings

of ACTSAV (ranking provinces from highest to lowest value of ACTSAV) and UNSAV (ranking provinces from lowest to highest value of UNSAV). This is intuitively obvious: the lower the value of P_A, the closer it will be to P_L and the greater the actual savings that will be realized. Since UNSAV = 1 - ACTSAV this explains the relationship between the predicted value of P_A and the ranking of UNSAV.

A comparison of the predicted rankings of P_A, and hence ACTSAV and UNSAV, presented in Table 12 with the observed values of ACTSAV and UNSAV, presented in Table 13, reveals that the predicted and observed rankings match pretty closely, with the noticeable exception of British Columbia. Ignoring British Columbia for the moment, we see Saskatchewan is able to capture about 50 per cent of the potential savings due to compulsory licensing, followed by Quebec and Ontario both with roughly 40 per cent each, then Newfoundland and Nova Scotia with about 20 per cent, with New Brunswick bringing up the rear, reaping virtually none of the potential benefits of compulsory licensing. The factor which probably accounts for British Columbia ranking joint first with Saskatchewan, given our earlier discussion in section III, is the use of actual acquisition cost in the determination of drug cost for reimbursement purposes to the pharmacist. In the remainder of this section we will discuss ACTSAV (and hence UNSAV), by province paying particular attention to any developments subsequent to the period covered by the estimates in Table 13 -- mostly 1983 -- as well as any evidence concerning the relationship between the

public plans which have been the topic of our attention and the rest of the prescription drug market in a particular province.

Saskatchewan. The major reason that Saskatchewan is unable to realize the full benefits of compulsory licensing through its SOC system is the practice of physicians writing no-substition prescriptions for the patentee brand, which is then dispensed at a much higher price. We re-estimated ACTSAV on the assumption that all of the prescriptions for the seven drugs in our sample were dispensed using the SOC price in the Saskatchewan Formulary.[73] The mean value of ACTSAV increased from 0.5213 reported in Table 13 to 0.9195.[74] This is consistent with our finding that ACTSAV for HPI is 1.00. The Saskatchewan Presciption Drug Plan (1984), in its brief to the Commission, remarked that one of the factors contributing to increased drug material costs, "relates to the policy of 'No Substitution'". The Plan estimated that the, "incremental cost of the drug materials due to this policy was $4.4 million in the 1983/84 fiscal year" -- about 10 per cent of the total expenditure on drugs by the province.

Among the provinces in our sample the high incidence of no-substitution prescriptions in Saskatchewan is unparalleled.[75] Quality problems with the brands listed as interchangeable in the formulary would not appear to provide an explanation for the high incidence of no-substitution prescriptions;[76] nor would the views of the medical establishment, which states that it is of overriding importance that, in relation to prescribing,

(a) The patient must be assured of receiving a specific product when, in the prescriber's professional judgement, such a decision is warranted,

(b) The quality, safety and efficacy of drug products must be assured by regulatory agencies. (Canadian Medical Association, 1984, p. 9).

Given the low incidence of no-substitution prescriptions in other provinces and the lack of any quality problems with interchangeable drugs it is difficult to understand what medical grounds warrant the large volume of no-substitution prescriptions for the patentee brand in Saskatchewan. Non-medical grounds would appear to include a successful marketing strategy of the patentees aimed "towards convincing prescribers to prescribe specific products 'no-substitution'"[77] and the fact that the province, not private individuals, pay directly for the cost of the drugs. In order to counteract the use of no-substitution prescriptions the province may wish to:

- increase the paperwork required of the physician in order for a no-substitution prescription to be written. This is currently the practice in Ontario;
- conduct a public education campaign aimed at physicians;
- In the case of those physicians who write a large volume of no-substitution prescriptions the cost implications could be specifically raised, with a request for the medical reasons necessary for such prescribing behaviour.[78]

However, more paperwork burden and education of physicians, perhaps with co-operation of the Saskatchewan Medical Association,

would seem more preferrable than singling out individual physicians for attention.

Ontario. The major factor that accounted for the Ontario provincial drug reimbursement programme (ODB) being able to capture only 0.4053 of the full benefits of compulsory licensing in 1983 was that the methods of cost determination (see section 3.2.5 above) resulted in formulary prices that were "too high".[79] Too high in the sense that virtually all of the ODB market, for the drugs in our sample, is supplied by the licensees (see Tables 9 and 10 above) and at a price to the pharmacist which is almost certainly equal to P_L. Hence, while the ODB programme was able to secure 0.4053 of the full benefits of compulsory licensing the pharmacists, in 1983, captured most, if not all, of the remaining 0.5947.[80] In 1983, the provincial government estimated that inflated ODB prices, across all multisource drugs, cost the government between $14.5 and $23.0 million or 8.7 per cent and 13.8 per cent, respectively, of Ontario's expenditure on all drugs, whether single or multisource, for 1983/84.[81]

The values of ACTSAV and UNSAV in Table 13 refer only to the ODB sector of the retail market in Ontario, which, as noted in Table 2, accounts for approximately 45 per cent of Ontario's drug bill. In the non-ODB market, for 1983, there are strong reasons to suppose that ACTSAV would be even lower than the ODB market. In the non-ODB market the pharmacist on receiving a brand name prescription has a choice: not to product select, in which case

typically the pharmacist will charge his usual and customary dispensing fee (in 1983/84 the non-ODB dispensing fee was $5.35) plus the cost of the drug as determined by the formulary; or product select and be able to charge the negotiated dispensing fee ($5.00 in 1983/84), plus the drug product cost for the least expensive interchangeable product in the pharmacist's inventory.[82] The incentive is therefore not to product select in the non-ODB market, which indeed appears to be the case.[83] In 1983/84 it would appear that in the non-ODB market approximately $22 million could be saved if multisource drugs were priced using the ODB mandatory price selection rules.[84] This is 10.8 per cent of total non-ODB expenditures on all drugs, whether multisource or single source.[85] Using this and some additional information, we recomputed ACTSAV for the whole retail market of Ontario -- ODB plus non-ODB -- and for 1983 the value was 0.2261, substantially below the 0.4053 for ODB only shown in Table 13.[86]

There has been much concern in Ontario over the disparity between the actual licensee price to the pharmacist (P_L) and the actual price which ODB reimburses the pharmacists (P_A). In recent years the provincial auditor has become concerned about this disparity. In his most recent Annual Report the discussion of ODB appears under the heading, "Excessive Costs Incurred re Payment under Ontario Drug Benefit Plan....."[87] Those administering the ODB have long been aware of the problem of the disparity between P_A and P_L. As a result a series of reports have been commissioned to study the problem. The latest of these, the Gordon Commission,

was completed in August, 1984[88] and is to provide the basis of reforming the pricing of multiple source or multisource drugs.[89] However, given Ontario's unsuccessful experience with attempts to implement the recommendations of the Bailey Committee report of 1978, on the same subject, any future reform is likely to be very difficult to achieve.[90]

Nevertheless, some progress would appear to have been made. As part and parcel of the creation of the Gordon Commission, the February, 1984 Ontario Formulary contained more realistic (i.e., closer to P_L) prices for thirty high volume multisource drugs.[91] All of the seven drugs in our sample were included in the thirty.[92] The reduction in price (P_A) for these seven can be gauged by comparing P_A for 1983 with the February, 1984 price:

		1983 Price per cap or tab	Feb, 1984 Price per cap or tab
cimetidine	300 mg. tabs	0.2060	0.0967
indomethacin	25 mg. caps	0.1310	0.1329
naproxen	250 mg. tabs	0.2980	0.2415
propranolol	40 mg. tabs	0.1020	0.0432
methyldopa	250 mg. tabs	0.0899	0.0566
flurazepam	30 mg. caps	0.0741	0.0441
allopurinol	100 mg. caps	0.0776	0.0436

where the February 1984 price is the lowest priced brand of each of the seven drugs as listed in the February 1984 provincial formulary. The drop in prices is quite dramatic. We re-estimated ACTSAV on the basis of the above February 1984 prices for P_A and

this index increased from 0.4053 in Table 13 to 0.8085 -- a substantial increase.[93]

Hence, it would appear that Ontario has gone a substantial way, at least in the ODB market, to realizing the full benefits of compulsory licensing. However, such an inference would seem unwarranted, for at least two reasons. First, as part of the arrangement concerning the lowering of prices on the thirty drugs the ODB dispensing fee was increased on all ODB prescriptions thus reducing the savings to the ODB substantially -- by at least 54.3 per cent.[94] Second, in attempting to implement the 1978 recommendations of the Bailey Committee, which were in essence the same as those of the Gordon Commission, the ODB dispensing fee was raised in return for more "realistic" formulary prices.[95] However, this did not work, since as Table 13 and the Gordon Commisssion's report demonstrates, the problem of differences between P_A and P_L still existed in 1983. Hence, it seems, if past history is a good guide to the future, the increase in ACTSAV in early 1984 recorded for our sample of seven drugs for Ontario, is but a minor hiccup, and in the next few years ACTSAV will drift downward and another Commission will be appointed to examine the pricing system.[96]

Quebec. The major reason Quebec has an observed value of ACTSAV in Table 13 of only 0.4405 would appear to be that the actual price paid, for a given drug, by the provincial drug reimbursement plan, was frequently substantially above the price paid by the

pharmacist for the given drug. ACTSAV is estimated for Quebec for the period Jan 1983-June 1984. During this period a number of changes took place in the Quebec plan, which are likely to have reduced P_A and hence the difference between P_A and the price paid by the pharmacist. Indeed, if ACTSAV were calculated for Jan-June 1984 for Quebec it is likely to be substantially above ACTSAV for the Jan 1983-June 1984 value in Table 13 -- perhaps by as much as 11.35 percentage points.[97]

Several of the drugs in the sample selected for analysis in this paper were priced in Quebec according to the median pricing rule,[98] described in some detail above. This is very similar to the scheme in Ontario,[99] and it would appear that for these drugs throughout the period 1983 onwards the pricing problems that have plagued Ontario were and are present in Quebec.[100]

The remaining drugs in our sample[101] were, in the first six months of 1983, priced according to the same general median pricing rules that applied to all drugs in the Quebec drug reimbursement plan.[102] However, in July, 1983 for a small number of high volume drugs which account for 10 per cent of the Quebec plan's total expenditure on drugs,[103] actual acquisition pricing was introduced.[104] The Quebec formulary lists a single price for all brands of each of these drugs by dosage form and strength.[105] The Quebec plan will reimburse up to this price, but if the pharmacist purchases the drug for a lower price, then this is the price at which the plan will reimburse.[106] Hence, in late 1983

and 1984 the price of these drugs should fall, compared with the first half of 1983.

There is little evidence on the relationship between the Quebec drug reimbursement programme and the rest of the Quebec market. As with Ontario the split between the public and private markets is approximately 45:55, respectively, but unlike Ontario there is no institutional incentive not to product select because the dispensing fee is lower when product selection takes place. Nevertheless, discussion with those knowledgeable of the Quebec market suggests that in the non-government sector, compared to the government sector, prices are higher, as in Ontario. The extent of this is, however, unknown. However, if we were to apply the same approach used for Ontario to Quebec, then ACTSAV for the whole of Quebec for our sample of seven drugs, would, on average, be 0.2946.

The Quebec drug reimbursement plan has undergone substantial change since early 1982 when median pricing was first introduced. Prior to that permissive product selection combined with payment of the brand dispensed at that manufacturer's price, led to little of the benefits of compulsory licensing being captured.[107] Table 13 showed that median pricing has led to 0.4405 of the potential benefits being captured. However, given the changes described above this is probably an underestimate in 1984. Nevertheless, if more drugs become listed at actual acquisition cost, the median price is made more 'realistic', and some attempt

is made to influence the non-government sector, then further gains will be made in Quebec.

Newfoundland. There are two major reasons why Newfoundland has a value of ACTSAV for 1983 of only 0.2262 in Table 13. First, of the seven drugs in our sample Newfoundland did not certify three as interchangeable in 1983. As shown in Table 7 the licensees made minimal headway in these three markets. Hence it is not surprising that the mean value of ACTSAV for these three drugs was essentially zero, while the mean value of ACTSAV for the four drugs which were certified as interchangeable was 0.3958. This is fairly close to the mean value of ACTSAV for Ontario and Quebec recorded in Table 13 for the sample of seven drugs. In both these provinces all seven drugs were certified as interchangeable and the various factors isolated in Table 12 are the same for Quebec, Ontario and Newfoundland, once the latter province has certified interchangeability. A second reason for Newfoundland experiencing a value of ACTSAV well short of unity, even on those drugs subject to interchangeability, is that the prices in the formulary are high, just as in Quebec and Ontario.

In the period subsequent to 1983 the Newfoundland prescription drug plan has taken two steps which are likely to see ACTSAV increase substantially. In the first instance the July, 1984 Newfoundland formulary contains much lower more 'realistic' prices.[108] We therefore re-estimated ACTSAV for the four drugs certified as interchangeable in 1983, with the result that a

substantial increase was observed - to 0.7990.[109] In the second instance, in the January, 1985 edition of the Newfoundland forumulary six of the seven drugs in our sample were certified as interchangeable -- all but flurazepam. Hence, the value of ACTSAV, if estimated for the seven drugs in our sample for early 1985, is likely to be much higher than the 1983 value recorded in Table 13.[110]

In Ontario and Quebec the non-government sector of the retail drug market is not subject to the same stringent mandatory price selection rules that apply to the public plan. As a result prices are substantially higher in the non-government sector of the market for these two provinces. This reflects the fact that these provincial governments have concentrated most of their efforts to realise lower drug prices on their own programmes, rather than the provincial market treated as a whole.[111] In Newfoundland, by contrast, the mandatory price selection rules of the government plan apply to <u>all</u> prescriptions dispensed in the province.[112] Hence the above commentary applies to both the public and private retail drug market in Newfoundland.

<u>Nova Scotia</u>. The reasons for Nova Scotia being able to realise only 0.1854 of the potential dollar savings of compulsory licencing for the seven drugs in our sample are not hard to find in view of our earlier discussion of this plan. Product selection legislation was not introduced in Nova Scotia until 1983, apparently in considerable part because of the opposition of physicians

(Chambers, 1982). However, a provincial formulary has been distributed to pharmacists and physicians in Nova Scotia since 1976, with the aim of providing "a listing of commonly-prescribed interchangeable pharmaceutical products of proven high quality" and prices to acquaint "practitioners with the comparative cost of prescription drugs".[113] The 1983 legislation was permissive. In view of the newness of the legislation, in the words of Pharmacy Association of Nova Scotia (1984, p. 2), which supports the legislation,

> At the moment it is estimated that less than 10 per cent of the drugs paid for by the government prescription plan are "generic". It is anticipated that this percentage value will continue to increase, as product selection becomes more widely accepted.

This percentage is similar to that recorded in Table 9 for the sample of seven drugs studied in this paper.

A second reason for the low value of ACTSAV in Table 13 for Nova Scotia is that, unlike Ontario, Quebec and Newfoundland provincial drug plans, Nova Scotia does not combine permissive product selection with mandatory price selection, but will reimburse for the brand dispensed at the price specified by the manufacturer in the formulary. Given the domination of the Nova Scotia market by the patentee brand the Nova Scotia drug plan will be paying prices at the high end of the scale.

In order to estimate the impact of reimbursing for the brand dispensed we re-estimated ACTSAV on the assumption that mandatory price selection of lowest priced brand -- as in Ontario and Newfoundland -- was in place.[114] This would have seen the value of ACTSAV increase from 0.1854 to 0.4058. The discrepancy between this higher value and unity suggests that Nova Scotia, like other provinces, has a problem in that prices quoted in the formulary are "too high". In the case of Nova Scotia it is anticipated that actual acquisition costs for the drug component of the prescription will be effective July 1, 1986, thus avoiding this problem.[115] Hence, there is some suggestion that even though Nova Scotia has to date reaped few of the benefits of compulsory licensing, the committment to actual acquisition cost by 1986 may change that somewhat. Interim measures might be, like Ontario and Newfoundland, the introduction of mandatory price selection of the lowest price brand and more "realistic" formulary prices.[116] Indeed, the former might be retained in some form after 1986.

New Brunswick. The New Brunswick Prescription Drug Programme has essentially been unable in the period for which ACTSAV was estimated in Table 13 -- Sept. 28, 1983 to March 23, 1984 -- to reap any of the benefits of compulsory licensing. In other words, during that time period New Brunswick was paying for the seven drugs in our sample the price that they would have been paid had compulsory licensing not existed since 1969.[117] The reasons for this are not hard to find given our previous discussion; permissive product selection legislation that is a virtual

dead-letter as shown by Tables 7 and 9 and confirmed by an Oct. 9, 1984 New Brunswick Pharmacists' Association memo, which reads, "...it became apparent that the use of Product Selection in New Brunswick has been minimal and is, in fact, the lowest of any province in Canada where there exists product selection legislation";[118] formulary prices based on smaller package sizes; reimbursement for the brand dispensed as per the manufacturers price in the formulary; and, for our sample of seven drugs, listing only three as interchangeable.[119] It is therefore not without irony that the Minister of Health for New Brunswick should write to the Commission that any proposed changes to compulsory licensing "...should ensure that market mechanisms which will have a moderating effect on prescription drug prices continue to exist".[120]

In the period subsequent to Sept. 28, 1983 - March 23, 1984 some changes have been made to the New Brunswick programme to realise lower drug prices. Formulary prices for a number of drugs are more 'realistic' and of our sample of seven drugs, the September, 1984 New Brunswick, Product Selection Formulary listed six as interchangeable. Nevertheless, while these measures will raise the value of ACTSAV, it is still almost certain that New Brunswick will not realize anywhere near the full potential savings of compulsory licensing. Stronger measures are needed, such as mandatory price selection.

British Columbia. The largest discrepancy between the observed provincial rankings of ACTSAV in Table 13 and those predicted on the basis of Table 12 (column headed "Overall Ranking") concerns British Columbia. The predicted rankings placed B.C. after Saskatchewan, Ontario and Quebec, whereas the actual value of ACTSAV for B.C., at 0.5447, was slightly above that for Saskatchewan (0.5213) and well above those recorded for Ontario (0.4053) and Quebec (0.4405). This result therefore provides something of a paradox.

The most important factor that would appear to account for the high ranking of British Columbia is the use of actual acquisition pricing. The B.C. Pharmacare programme appears to be able to effectively eliminate the problem that plagues many of the other provinces -- that the formulary prices are well above the price the pharmacist pays for the drug. In B.C. actual acquisition cost is achieved by careful monitoring of pharmacy drug costs and, where appropriate, repayment of overbilling to Pharmacare.[121] Furthermore, the use of actual acquisition cost is supported by British Columbia pharmacists, who describe actual acquisition cost as follows:

> Drug cost to Pharmacare has always been only that. Sometimes referred to actual acquisition cost (AAC), it is the actual price paid to drug suppliers except for minimal discounts intended as an inducement for prompt payment with no profit or markup involved.
>
> Claims from each pharmacy are expected to reflect true cost. Rather than the third party agency declaring through publications what it will accept for drug cost, Pharmacare

> merely monitors drug cost submissions and through general audit and the occasional on-site audit verifies that submissions are accurate. This process is logical since it should be the purchaser not the payer who knows what actual drug costs are.
>
> Since the introduction of Universal Pharmacare on June 1, 1977 virtually all prescriptions in the Province are priced on the basis of actual drug cost. In this respect Pharmacare has had a major influence on how prescriptions are priced in British Columbia. (British Columbia Pharmacists' Society, 1984, p. 3).

A number of other reports have suggested B.C. has low drug prices.[122]

Nevertheless if measures were taken to increase licensee market penetration, then even more of the benefits of compulsory licensing would be realized in B.C., since, as Table 9 shows, the discrepancy between the licensee market share measured in quantity and price is sufficiently high to suggest that patentees products command a premium in B.C.[123] If the actual licensee prices charged in B.C. were applied to <u>all</u> of Pharmacare's prescriptions for the seven drugs in our sample, then ACTSAV would increase from 0.5447 to 0.8160.[124] Apparently there have been some attempts to increase product selection in B.C. by encouraging the "labelling [of] all prescriptions for single ingredient drugs by their non-proprietary or generic names rather than their brand names."[125] Pharmacare has also encouraged "...the exercise of the product selection prerogative whenever practical and possible for all prescriptions".[126] Hence in 1984 and 1985 ACTSAV for B.C.

might be higher than 0.5447. However, exhortation to pharmacists to increase product selection may be insufficient to increase licensee market penetration and hence lower costs.[127]

4.4 Some Qualifications?

There are two potentially important qualifications that can be raised concerning the estimates of the potential and actual benefits of compulsory patent licensing and associated provincial programmes presented in this paper. These qualifications both start with the premise that these results are plausible, but argue that they may be misleading to the reader who accepts the findings at face value. One qualification is that the dispensing fee is lower in some provinces because pharmacists have captured some of the benefits of compulsory licensing, while the second qualification is that patent owners raise prices on single-source drugs to compensate for the revenue loss due to the impact of compulsory licensing. We discuss each in turn.

The price of a prescription is divided into two parts: the dispensing fee and the drug cost. It is commonly accepted that the dispensing fee represents the compensation to the pharmacist for his professional services. The fee is set (for the government sector) usually after some discussion and negotiation between the provincial government and pharmacy association.[128] The drug cost is priced separately according to the rules in Tables 1 to 3. In theory at least the drug cost should be just that -- the price the

pharmacist pays to the manufacturer or wholesaler for the drug. The pricing of a prescription in two parts, in contrast to the traditional mark-up over cost, was introduced to remove the incentive to dispense high price brands and thus not place lower priced brands at a disadvantage.

However, with respect to drug cost, theory and practice do not always coincide. While it is true that in British Columbia and Saskatchewan the drug cost to the pharmacist is essentially the amount for which he is reimbursed by the provincial government, this is not the case, in varying degrees, for all of the other provinces in our sample. For this latter group of provinces the government reimbursement price is above the drug cost to the pharmacist. In order to see whether this results in lower dispensing fees for these provinces would be a very difficult task indeed. Attention would have to be paid to all of the other determinants, such as the relative bargaining strengths of the province and the pharmacists, the supply of pharmacists, the importance of chains vs. community pharmacists, etc. It is beyond the scope of this paper to complete such an exercise. Nevertheless, there is some evidence which can be used to throw light on the issue.

Two provinces which, in view of our discussion in section 4.3, would be good candidates to compare, are Ontario and British Columbia. In British Columbia there is actual acquisition pricing while in Ontario the problem of the price-spread is well

documented. Indeed, the Ontario Pharmacists' Association takes the position that:

> ...although pharmacists do not endorse the practice of spread-pricing, the revenue they receive from it has been necessary to offset, first, the lack of any purchasing advantage on some drug products, particularly single-source products, and, second, a negotiated fee which is less than adequate. (Gordon, 1984, p. 53).

There would appear to be some, prima facie, evidence to support their position, since in 1983 the ODB dispensing fee was $4.56 while in British Columbia it was $5.14.[129] However, there is one important difference between British Columbia and Ontario which this comparison fails to take into account: in British Columbia a dispense as written policy is followed, whereas in Ontario a dispensing fee is collected for every one month's supply. In other words, if a patient enters a pharmacy in British Columbia with a prescription for two month's supply then the province will pay (in 1983) $5.14 plus the drug cost. In contrast, in Ontario under the ODB, two dispensing fees of $4.56 will be collected plus the drug cost. Since both of the provincial governments provide free drugs to those over 65, many of whom are on long-term maintenance drugs, this factor should be taken into account in comparing dispensing fees.

In a careful study for the Ontario Ministry of Health and the Ontario Pharmacists' Association, Woods Gordon (1981a, 1981b) undertook to examine the implications, in terms of the number of

dispensing fees, that would be collected if Ontario moved to a dispense as written policy. Furthermore, in deriving the final result, the Woods Gordon study examined the British Columbia experience with dispense as written. Using the results of Woods Gordon for 1980-1982 to make the Ontario fee comparable to that in British Columbia, would result in the Ontario fee increasing from $4.56 to $5.31[130] -- 3.3 per cent greater than the British Columbia fee. Hence, it would appear in the province where the arguement concerning dispensing fees is most likely to prevail, the evidence is inconsistent with the view of the pharmacists.[131]

The argument over dispensing fees is not so much that the potential benefits of compulsory licensing are not realized as that when both drug cost and dispensing fee are considered together, more of the benefits are realized than is perhaps obvious at first sight. In contrast, the argument that firms subject to compulsory licensing raise prices on single source drugs suggest that all of the benefits of compulsory licensing are vitiated because of the pricing policy of drug firms. In earlier work this was investigated and no evidence was found to sustain the hypothesis.[132] More recent evidence, including Kennett (1982), does not change that view.[133] Hence, in sum, it would appear that neither of the potentially important qualifications of the findings presented in sections 4.1 to 4.3 need apply to our results, although clearly much more work would be required before a definitive result could be derived.

V SUMMARY AND CONCLUSIONS

At the beginning of this paper we outlined the task to be undertaken: to examine the extent to which the reduction in prices at the level of the manufacturer consequent upon the introduction of compulsory licensing to import in the 1969 amendments to the Patent Act have been passed on to the consumer. We undertook to answer this question by reference to a sample of seven high volume multisource drugs -- indomethacin 25 mg. caps, flurazepam 30 mg. caps, naproxen 250 mg. tabs, propranolol 40 mg. tabs, methyldopa 250 mg. tabs, cimetidine 300 mg. tabs, and allopurinol 100 mg. tabs -- for seven provincial retail markets -- British Columbia, Saskatchewan, Ontario, Quebec, New Brunswick, Nova Scotia and Newfoundland -- paying particular attention to the provincial drug reimbursement programmes in each province. In addition, we examined the buying records of a large hospital purchasing group -- Hospital Purchasing Incorporated, Toronto.

Our results, for 1983, showed that the maximum reduction in expenditure that could have been realised by the introduction of compulsory licensing was, on average, 65 per cent for the seven drugs in our sample. In other words, for every dollar that would have been spent on these drugs had they been accorded full patent protection, compulsory licensing allowed or permited a price reduction of 65¢ to 35¢. This suggests that dramatic savings are available to Canadians.

Our results, however, indicated that of the potential dollar savings on the seven drugs in our sample, on average, for Canada as a whole for 1983 for both retail and hospital markets, the realised dollar savings would appear to be about 50 per cent, if anything somewhat less.[134] In 1984, as our discussion in section 4.3 makes clear, this might have increased by several percentage points. Hence of the potential 65¢ on the dollar that could be saved about 33¢ are realised.

The aggregate figures mask a substantial variation by individual market. At one extreme is a large buying group of hospitals in Toronto, Hospital Purchasing Incorporated, which has realised all the potential benefits of compulsory licensing, while at the other end of the scale, New Brunswick, which has realised few of the benefits of compulsory licensing. In between are provinces such as Ontario (between 0.2261 to 0.4053) and Quebec (between 0.2946 and 0.4405), with the most successful provinces being British Columbia (0.5447) and Saskatchewan (0.5213).

An examination of individual markets revealed four major reasons as to why the full benefits of compulsory licensing have not been realised.

- Physicians writing no-substitution prescriptions. This problem is particularly important in Saskatchewan, where the writing of no-substitution prescriptions for patentee brands, much higher priced than licensee brands, has raised that province's <u>overall</u> drug bill 10 per cent.

- The interaction between private and public drug programmes, such that the provincial government sets rules and procedures that result in it being able to realise some of the benefits of compulsory licensing, while the private sector is subject to a set of rules that results in it paying higher prices and realising less of the benefits. This situation occurs, for example, in Quebec and Ontario, but not Newfoundland and Saskatchewan, where one set of rules applies to the whole provincial market. In Ontario this resulted, for example, during the first six months of 1983, in the Ontario Drug Benefit Programme paying a little more than 1.91 cents per tablet of diazepam 5 mg., but Green Shield Prepaid Service Ltd. paying 4.27 cents.[135]

- Prices in provincial government formularies -- used as the basis to reimburse pharmacists -- that are above the price the pharmacist pays for the drug. In other words, some of the benefits of compulsory licensing accrue to the pharmacist, not the provincial government or consumer. This appears to occur in most provinces (except British Columbia and Saskatchewan) although some steps have been taken in 1984 (and early 1985) to curb this practice. It is estimated, for example, that for Ontario in 1983, that the provincial government paid out an extra $14.5 million to $23.0 million because of inflated prices on multisource drugs,[136] while a survey in Manitoba for 1982 revealed that pharmacists, on formulary drugs, charged, on average, $4.16 per prescription, but actually purchased the drugs for $3.19.[137] It might be noted, parenthetically, that the price-spread problem on drugs seems fairly widespread -- from California[138] to the U.K.[139]

- In the two provinces in our sample of seven, New Brunswick and Newfoundland, certain high volume multisource drugs were not listed as interchangeable in 1983, thus the province was denying itself the benefits of compulsory licensing for these drugs. However, by 1985 most of these were listed as interchangeable and hence the problem largely disappeared.

In the main body of the paper we outline possible policy changes for most of the provinces that could be be adopted so as to facilitate the realisation of more of the benefits of compulsory licensing. Indeed, as we detailed in section 4.3, recent moves by

a number of provinces, to increase these benefits have been made. Nevertheless there remains much scope for further gains.

The suggestions for policy changes are made within the existing policy framework and draw upon the experience of the various provincial schemes. An important question that needs to be asked is whether this framework is the optimal one available to policy makers. As we will suggest below there are strong reasons for suggesting the answer to this question is "no", and that a much greater role for the market should be considered. In Appendix C we outline some suggestions which attempt to retain the more successful features of the current system while injecting more competition at the retail level. Further discussion is contained here and in Gorecki (1981, pp. 177-189), where these suggestions were originally made.

Our discussion of the retail drug market in sections II to IV established two important features: a very significant and rising role for provincial governments, both as providers of drugs free for certain groups of the population and as the actor with ultimate legal responsibility for setting the rules of the game at the retail level, both for itself and the private market; and a market place that, while structurally competitive, typically shows few signs of competitive behaviour. Gordon (1984, pp. 58-59) has commented recently on the competitive behaviour in the Ontario market, which would seem typical of many retail markets in Canada,

> In the Commission's view and, we believe, in the view of at least some of the system participants, the fundamental structural problems of the current programmes and policies are the singular lack of effective competition throughout the retail prescription market and, in those instances when some competition exists, the barriers preventing the benefits of such competition from being passed on to consumers. In short, while some elements of the present structure promote competition, other elements hinder it. The elements which hinder it are stronger than those which promote it -- thus the overriding objective of reasonable prices for prescription drug products and services is not achieved to an acceptable level.

It might be noted, parenthetically, those who have tried to take advantage of the competitive forces that do exist have achieved the greatest benefits from compulsory licensing -- British Columbia, Saskatchewan and Hospital Purchasing Incorporated.

There is a distinct possibility that as the role of government increases, combined with the general lack of competition in the retail market and the differences between pharmacy and provincial governments over compensation to pharmacists, that the retail drug industry will become a highly regulated industry. Cost surveys to determine dispensing fees and drug cost, based upon some "average" or "individual" or "reasonably efficient" retail operation may be established,[140] with, eventually, limits on the number of new pharmacy operations. However, there are well-known problems with such systems as the literature on regulated industries such as agricultural marketing boards amply demonstrates.[141]

Reliance on short-run accounting costs in determining pharmacy costs may, for example, find that costs are well below revenue. Does this indicate that fees be dropped and drug costs lowered? Not necessarily. The short-run profit may be a market signal suggesting there is considerable demand for the services of pharmacists, due, for example, to the increasing numbers of old people who are heavy consumers of drugs -- entry should therefore take place. On the other hand, the profit may indicate that pharmacists' associations are able to operate as effective bargaining agents for their members and extract a rent from provincial governments. The result may be entry but this will dissipate the profit and result in an "excessive" number of pharmacies, eventually all earning a normal rate of return. Accounting costs are therefore likely to be very difficult to interpret, and more detailed data will not likely solve the problem.

In Appendix C we suggest some reforms that would see much more competition introduced in pharmacy. These call for a lifting of restrictions on drug and dispensing fee advertising, which according to Cady's (1975, p. 129) study of the U.S. results in, "excess costs ...[and] prices significantly above average costs." We believe these suggestions are desirable in and of themselves if the full benefits of compulsory licensing are to be realized and pharmacy is to be operated as an efficient sector.

Movement toward greater competition is not likely to be easy. To the extent past policies have led to unsustainably high costs then pharmacists will claim these "entitlements" should be protected in any move toward greater competition. One of the better examples concerns the dispute in Ontario over 30 day supply vs. dispensed as written prescriptions. This is a good example because attempts have been made to change the 30 day rule to dispense as written, but it also shows how an "entitlement" once given, even if, as in this case, almost by accident, it becomes very difficult to withdraw without some financial compensation. In the accompanying boxed insert, titled "Prescription Quantity" we quote from an Ontario government memorandum of July 1978 which graphically illustrates this point. The Bailey Committee[142] recommended a dispense as written policy in May 1978, as did the Ontario Standing Committee on Public Accounts (1980, p. 37), with the Ministry of Health in apparent agreement but no negotiated settlement between pharmacy and the government was reached, even though the Woods Gordon (1981a, 1981b) study was conducted at the behest of both parties. The Gordon Commission[143] made a similar recommendation in August, 1984. Hence, some determination and ability to compromise may be required.

. . .

PRESCRIPTION QUANTITY

Over the past several months an increasing number of complaints have been received from both Drug Benefit recipients and physicians relating to "pharmacists' refusal to provide more than one month's supply of drugs, although the prescriber has specified a greater quantity".

A typical complaint states "Why is the government wasting my money, I used to purchase 100 Hydrochlorothiazide for $3.95. I take two a week, so 100 lasts me about a year. Now the pharmacist gives me only eight or ten at a time, it must be costing the government ten times as much." The above is an actual complaint and in fact if the pharmacist charges the maximum allowable dispensing fee ($2.95) plus the cost listed for 100 Hydrochlorothiazide 50 mg at $1.25 the prescription would cost $4.20. On the other hand, dispensed at the rate of ten per month, for twelve months, the cost would be $1.25 drug cost plus $35.40 (12 x 2.95) = $36.65. This example indicates that the government may have paid $32.95 too much.

Prior to the beginning of Drug Benefit the matter of prescription quantity was the subject of a meeting between representatives of the Ontario Medical Association, the Ontario Pharmacists' Association and the Consumers' Association of Canada, Ontario Branch. As a result of discussions among these groups, the following definition of prescription quantity was adopted for the Parcost program: "Prescription quantity: the professional fee will apply to the quantity ordered by the prescriber. Exceptions to this will be allowed, provided the pharmacist explains why a fee in excess of the stated maximum is being charged prior to the dispensing of the prescription."

When Drug Benefit began in September 1974, eligibility was based on financial need which was determined monthly. With the possibility of these benefits being terminated at any time, pharmacists were instructed to dispense only one month's supply of medication to ensure that this program would not be abused by persons temporarily in receipt of benefits.

On August 1st, 1975, the Drug Benefit was expanded to include all citizens 65 and over with eligibility granted on a continuing lifetime basis. Because of this the policy of limiting the supply of drugs to the one months period of eligibility was no longer necessary.

In the Ministry's negotiations with the pharmacists, the question of whether the quantity dispensed should be that required for one month or for several months was debated at great length. It was the pharmacists' view that a higher fee than that finally negotiated would be required if the quantity was greater than one month.

The Drug Benefit Participation Agreement that was drafted between the Ministry of Health and the Ontario Pharmacists' Association states that the quantity prescribed shall be sufficient for one month's course of treatment except where the course of treatment is less than one month, in which case the quantity provided shall be sufficient for the course of treatment.

There is also an exemption clause built into the agreement that allows the dispensing of a quantity that is greater than the quantity required for one month's treatment where the prescriber specified the quantity. Therefore, if more than one month's supply is prescribed for a maintenance drug, nothing prevents the pharmacist from dispensing the quantity prescribed.

In summary, the present situation stands thus:

1. A physician may prescribe whatever quantity deemed necessary for a patient up to a maximum of six months. In most cases today, physicians do not actually write a prescription, but order most drugs, particularly refills, over the phone. It is a misconception that only a one month's quantity may be prescribed and that a patient must return each month to the physician's office for a new prescription.

2. No more than one dispensing fee per month will be paid on those drugs identified as maintenance drugs in the Drug Benefit Formulary. For products not classed as maintenance drugs, e.g., antibiotics, one fee is allowed for each quantity dispensed as prescribed for the particular course of therapy. Therefore, more than one dispensing fee may be paid for the same antibiotic in a particular month.

3. If more than one month's supply is prescribed for a maintenance drug, pharmacists may exercise their professional judgement and dispense the quantity prescribed, up to a maximum of 6 months at any one time. In order to control drug abuse or misuse, many pharmacists have adopted the practice of dispensing only one month's quantity at a time, and unfortunately when challenged why, they have been telling the public that it is the drug plan that limits the quantity they can obtain at any one time.

Source: Ontario Ministry of Health, memo "RE: Ontario Drug Benefit," July, 1978, pp. 8-9.

In conclusion, our results clearly demonstrate that substantial steps have been taken in lowering drug costs by successful utilization of the opportunities offered of compulsory licensing. This success is, in part, due to the existence of several distinct provincial drug reimbursement programmes and price/product selection rules which permit provinces to learn from each other -- in 1984 several provinces noticed that others were conspiciously successful in obtaining lower prices and were able to obtain the same prices[144] -- and yet, at the same time, adapt schemes to their own particular circumstances -- the tendering system in hospitals and Saskatchewan may not work well in larger provinces such as Ontario and Quebec. Nevertheless, there are still considerable gains to be made and the pressures for deficit reduction may provide just enough of an impetus to bring about change or, at least, focus serious attention on future policies of government toward pharmacy and drug costs.

Notes

1 For a discussion of the background to the introduction of compulsory licensing and its subsequent development and impact to 1980 see Gorecki (1981).

2. The Patent Act does not restrict the category or classification of drugs for which a compulsory licence application may be granted. As a result not all of the licensed drugs can be classified as "prescription". This study concentrates upon prescription drugs in examining the impact and effects of compulsory licensing. This choice was made for several reasons. First, the various government inquiries conducted into the price of drugs in the 1960's, which led to section 41(4) being enacted, appeared to be principally concerned with prescription drug prices (Canada, Director of Investigation and Research, 1961; Canada, Restrictive Trade Practices Commission, 1963; Canada, Royal Commission on Health Services, 1964, 1965; and Canada, Special Committee of the House of Commons on Drug Costs and Prices (1967)). Second, of the 196 licenses issued by December 31, 1983, 181 (or 92.3 per cent) were for prescription drugs, while of the 70 licensed drugs, 58 (or 82.9 per cent) were classified as prescription. (See Appendix A for details). Hence, it would appear that the main impact of compulsory licensing is likely to be on the prescription drug market, not veterinary drugs or those that can be purchased by the patient, without a prescription, from the pharmacist (i.e., non-prescription drugs, none of which, in any event, resulted in the licensee selling a drug product in competition with the patentee as of December 31, 1983). Third, it has been estimated that of the various categories of drugs delineated above, prescription drugs are by far the most significant in terms of sales. The relative proportions are 100:56:13, as between prescription, non-prescription and veterinary, respectively. (See Canada, Department of Industry, Trade and Commerce, 1980, p. 8). Thus, the prescription drug market is not only the most important in terms of licenses, but also in terms of economic size. Since attention is being confined solely to prescription drugs, unless otherwise stated, the term "drugs" will be understood to refer to prescription drugs throughout the text and tables.

3 These are described in some detail in Gorecki (1981, pp. 9-23) and below in this paper.

4 See the studies by Plett and Jackson (both unpublished, but summarized in Gorecki, 1981, pp. 122-126), Fulda and Dickens (1979), Fowler and Gordon (1984), Kennett (1982), Canada, Department of Consumer and Coporate Affairs (1983) as well as some of the briefs to the Commission, including Canadian Drug Manufacturers Association (1984a) and National Anti-Poverty Organisation (1984).

5 Gorecki (1981) makes some attempt in this regard for several provinces, while Gorecki and Klymchuk (1980) concentrate more narrowly upon Ontario.

6 See, for example, Hirshleifer (1976, pp. 438-462).

7 See, Canada, Department of National Health and Welfare (1980, pp. 20-21) for details.

8 This is a relatively recent occurrence. For details see Temin 1980) where the U.S. experience is discussed.

9 See Walker (1971, pp. 8-11).

10 Only a registered pharmacist may dispense a prescription drug upon receipt of a physician's prescription. A professional body, created under provincial law, is normally responsible for overseeing the discipline, registration and conduct of pharmacists on behalf and in the interests of the public.

11 Using Ontario as the example. For details see Ontario, Ministry of Health (1984, pp. 79-80).

12 Canadian Council of Blue Cross Plans (1983, p. 6).

13 Gordon (1984, pp. 43-44), which states that about 20 per cent of all prescriptions are written generically (i.e., open prescription) while 40 per cent are brand-name. If all open prescriptions are for multisource drugs then prescriptions for multisource drugs would be 60 per cent of all prescriptions. The 20 and 40 per cent would appear to come from Milovanic's (1983) extensive survey of Metro-Toronto pharmacies in the 1970s. (At one point Milovanic (1983, p. 88) appears to infer that for 1979, 51.7 per cent of all prescriptions were for multisource drugs.) The remaining 40 per cent are brand-name prescriptions. The 40 per cent figure is consistent with the estimate of Ontario College of Pharmacists (1984, p. 14), which refers to product selectable prescriptions. In conversation with the College it appears the term product selectable refers only to brand-name prescriptions.

14 The percentage of open prescriptions is based upon data for Ontario (Milovanic, 1983, Table 1a, p. 44; Gordon, 1984, p. 43) and Manitoba (Davis, 1983, Table 1, p. 419); no substitution data for Ontario (Milovanic, 1983, Table 1a, p. 44; and information provided for the Ontario Drug Benefit Programme by the Ontario Ministry of Health to the author); Quebec (information supplied for the Quebec drug reimbursement programme by the Régie de l'assurance-maladie du Québec to the author) and Manitoba (Davis, 1983, Table 1, p. 419); while brand name is a residual from the above estimates. As we note below in Saskatchewan the incidence of no-substitution prescriptions is much higher than 1 per cent.

15 See Canada, Department of Health and Welfare (1984, Table 2, p. 32, and Table 56, p. 86). It should be noted that the percentages include the dispensing fee of the pharmacist.

16 PMAC (1984a, Table 1, p. 7), based on IMS data, provide total hospital and retail drugstore sales separately. To estimate these three percentages (i.e., 25.3, 41.9 and 54.0) we apply the 5 per cent, 25.9 per cent and 43.3 per cent retail percentages to the column titled "Drugstores", which is then added to the column total for "Hospitals" and divided by total drug sales in Canada. For 1970, PMAC (1984a, Table 1, p. 7) provides no breakdown between "Drugstores" and "Hospital" so the ratio 22:78 is taken, based on subsequent years' data. It should be noted that the PMAC (1984c, pp. 10-11) also estimated the share of the total Canadian drug market accounted for by public programmes and concluded the percentages for 1970, 1975 and 1981 were, respectively, 19.0, 37.6, and 51.8. These are somewhat lower than the public and reflect a slightly different approach. However, by 1981 the difference between the two methodologies is only 2.2 percentage points.

17 See Canadian Council of Blue Cross Plans (1983, p. 2).

18 Gordon (1984, p. 33).

19 See text Table 3. In Ontario the population covered by the public programme, Ontario Drug Benefit (ODB), had on average, in 1983-84, 19.2 prescriptions compared with 4.3 for the rest of the population. The ODB covered only 14 per cent of the province's population. See Gordon (1984, Appendix C, np). In Quebec those over 65 years of age participating in the government drug reimbursement programme, on average, in 1983 received 23.6 prescriptions costing a total of $230.55, while for those under 65 receiving benefits under the Quebec programme the corresponding numbers were 12.0 and $116.08, respectively. See Quebec, Régie de l'assurance-maladie du Québec (1984, Tableau 68, pp. 199-200).

20 Two points should be noted about the 10 per cent figure. First, on the basis of footnote 19, it seems reasonable to assume that the 15 per cent of the population not covered by any plan consume 10 per cent of drugs. Even if 15 per cent were used none of the conclusions would change substantially. Second, the 10 per cent figure understates the degree to which consumers pay directly for a drug, since drug reimbursement programmes, in both the public and private sector, include co-payment features. For the public sector these are summarised in Table 2. Nevertheless it seems reasonable to infer that a very substantial proportion of drugs are not paid for, in whole or in part, by the consumer.

21 The breakdown in drug sales between the various participants in the retail drug market is based upon the data presented earlier in this section. All percentages were rounded.

22 See PMAC (1984a, Table 1, p. 7) for split between hospital and retail drug market sales. Note to the extent that hospitals are more successful in obtaining lower prices, these figures probably underestimate the significance of the hospital market, if sales were estimated using a common set of prices for both the retail and hospital market.

23 These are summarized as of the date 1970s in Gorecki (1981, pp. 279-280). It would appear little of substance has changed since then.

24 See Economic Council of Canada (1979, pp. 23-27).

25 See note 19 for details.

26 See, for example, Gorecki and Klymchuk (1980) and R vs The Metropolitan Toronto Pharmacists' Association, unreported judgement, Supreme Court of Ontario, November 27, 1984, concerning the interaction between Toronto pharmacists, the Ontario government reimbursement programme, ODB, and a private third-party drug programme, Green Shield.

27 This gap is partially filled for those provinces by the annual publication of the Canadian Pharmaceutical Association, the Compendium of Pharmaceutical Specialities, which besides listing information concerning the drugs' uses and side-effects also names the various firms which sell the drug. (However, see Lexchin, 1984, pp. 145-149, which suggests this source has some important shorcomings.) In addition pharmacists in these two provinces may refer to formularies published elsewhere in Canada.

28 The committee will evaluate each brand of a drug based upon data provided by the federal Department of National Health and Welfare, Bureau of Drug Quality Assessment, and, in some instances, additional information provided directly by the manufacturer. See the various provincial formularies which usually contain more information in the introductory part of the document.

29 In the latter case the formulary has been used as a listing of all drugs for which the provincial government will reimburse under its plan.

30 It should be noted that for Manitoba and Newfoundland whether or not product selection takes place, the pharmacist can charge no more than the lowest price in the formulary for a group of interchangeable pharmaceutical products. We refer to this as mandatory price selection.

31 Some product selection does apparently take place in the central dispensary operated by the P.E.I. government.

32 An illustration may clarify the issue. In the July 1983 Ontario formulary (Ontario, Minister of Health (1983, p. 33)) five brands of methyldopa 250 mg. tabs are listed:

BRAND	PRICE PER UNIT
Methyldopa	0.0922
Apo-Methyldopa	0.0940
Novomedopa	0.0960
Dopamet	0.1144
Aldomet	0.1229

If the MAC was set at the lowest price -- 0.0922 -- then irrespective of whether Methyldopa or Apo-Methydopa etc. is dispensed the provincial government will only reimburse 0.0922. In one province, Quebec, the MAC is set at the median price, in this case 0.0960.

33 These are: cimetidine, various dosages; isosorbide dinitrate, various dosages; ibuprofen, various dosages; naproxen, various dosages; propranolol, various dosages; and hydrochlorothiazide/ triamterene 25 mg/50 mg. (See Quebec, Régie de l'assurance-maladie au Québec (1983, pp. 213.A-1 - 213.A-6)).

34 The exception is the generic section of the industry. In the U.S., which accords full patent protection to drugs, it is estimated that offpatent, non-branded generics will experience substantial market growth in the near future. In 1982, for example, generic prescriptions (or open to use our terminology) accounted for 14 per cent of prescription units. (See Becker Parbas, 1984). By 1988 it is expected that generic drug firms will account for over one-fifth of the U.S. drug market (Economist, 1985).

35 For further details of facts in the sentence see Gorecki (1981, pp. 25-47).

36 Prior to 1969 the ability to obtain a license to manufacture existed. However, due to the smallness of the Canadian market few licenses were taken out under the pre 1969 legislation. See Gorecki (1981, for details).

37 A firm may hold more than one license for a particular drug -- there may be multiple patent holders, necessitating a separate license for each patent holder, and/or the patent owner(s) may be granted additional patents relating to a drug subsequent to the original licensee application, again necessitating additional licenses. Throughout this paper all such licenses are consolidated into one. In other words, we are concerned with the number of firms with the right, because of compulsory licensing,

to sell a particular drug, irrespective of the number of actual licenses held, by a particular firm.

38 See Canada, Department of Consumer and Corporate Affairs (1983, p. 35).

39 For example, Gilcross Ltd. went bankrupt. For the situation in 1978 see Gorecki (1981, Table 4-1, p. 71 and Table 4-2, p. 72).

40 For one licensee's experience in this area, which both manufactured the bulk active ingredient and sold some final dosage forms, see Canada Packers Chemicals (1984).

41 For example, Novapharm Ltd. took a license out against metoprolol tartrate on May 5, 1983 but, as yet, has not marketed its own brand.

42 See Canada, Department of Consumer and Corporate Affairs (1983, p. 29). The $105 million and $125 million figures refer to all pharmaceutical sales of the licensees, not just their licensed drug sales.

43 See Bond and Lean (1977) on this issue.

44 See PMAC (1984b, p. 8) concerning Apotex Inc., where for the drugs triazide, indomethacin and metoprolol tartrate the costs of receiving a Notice of Compliance for Apotex Inc. were $75,000, $50,000 and $50,000 respectively.

45 On these costs see, for example, Hansen (1977).

46 Canada, Department of National Health and Welfare (1984, Table 2, p. 32, Table 26, p. 56 and Table 28, p. 58). The percentage in the text refers to prescribed drugs.

47 The seven were selected by T. Brogan of the Federal Department of Consumer and Corporate Affairs for the development of system of exchanging drug information between provinces. The author contacted each province in turn to gain access to such data. In the case of Quebec and Ontario the provincial government had to be contacted directly for such data. For further details see Appendix B.

48 One licensee which supplies a number of firms explained the rationale behind this as follows: frequently such firms were filling niches of the market where the licensee would be unlikely to be able to penetrate very far.

49 See Canada, Director of Investigation and Research (1961), Canada, Restrictive Trade Practices Commission (1963), Canada, Royal Commission on Health Services (1964, 1965) and Canada,

Special Committee of the House of Commons on Drug Costs and Prices (1967).

50 See, for example, Teeling-Smith (1975), but as a useful counter-point on some of the points made see U.K., Monopolies Commission (1973).

51 Often it is possible, through special requisitions and procedures, for the physician to prescribe a drug not in the formulary and have the drug reimbursed under the provincial government drug plan.

52 Apotex Inc. vs Attorney General of Ontario, Minister of Health and Lieutenant Governor in Council, unreported judgment, Supreme Court of Ontario, June 29, 1984, p. 2.

53 See, for example, Bristol-Myers Pharmaceutical Group (1984, p. 9) and Astra Pharmaceuticals Canada Ltd. (1984, p. 12).

54 Although median pricing was the rule in Quebec this did vary somewhat for some of the seven drugs in our core sample. Nevertheless these variations did not seem important enough to put Quebec in a separate category. See section 4.3 below for a detailed discussion.

55 It should be noted that the importance of no-substitution prescriptions in Saskatchewan is the exception rather than the rule. (See section 2.2.1 and footnote 14.)

56 See also Appendix B where the no-substitution market is discussed in more detail, albeit in a somewhat different context.

57 This assumption seems reasonable in view of the "low" standard deviation reported in Table 9, except, of course, for Newfoundland for reasons discussed in the text.

58 It is not clear, however, why such a strategy would have been more successfully used in Quebec by the patentees. Another possible reason is that for indomethacin 25 mg. caps there are only two brands, one licensee, and one patentee. Hence median pricing does not apply. The average actual price paid for indomethacin 25 mg. caps by the Quebec government is much closer to the patentee than licensee price, suggesting the patentee holds most of the market. If we assume, for example, that for this drug the licensee share is only 0.10, then in Table 9 the market share of the licensees excluding indomethacin 25 mg. caps would increase from 54.71 to 62.16.

59 There is some evidence the patentee price is not changed, if at all, until actual entry takes place. See Gorecki (1981, pp. 120-126). There is some debate over whether the price is

higher, however, because of the threat of entry. See PMAC (1984c, p. 50), Gorecki (1981, pp. 164-170) for further discussion.

60 No-substitution prescriptions are discussed further in Appendix B below. Some evidence that patentees gradually reduce their price is to be found in Gorecki (1981, pp. 120-127). The PMAC (1984c, p. 51) comments,

> When a generic company enters a market with a copy product, it appears that innovator companies can and have followed basically two completely different strategies: one strategy that appears to have been used is where the innovator attempts to retain sales and prescription share of the market by being price competitive; the other strategy, perhaps that most commonly used, is for the innovator to hold the line on price, which serves to retain margins at the expense of unit volume.

Perhaps the most conspicuous example of the former resulted in Hoffman-La Roche Ltd.'s conviction for predatory pricing. (See Gorecki, 1985, for details.) More recently both Upjohn and Syntex have formed subsidiaries with the sole aim of competing in terms of price with the licensees. (See Upjohn Co. of Canada, 1984, and Syntex Inc., 1984, for details.)

61 See Hoffman-La Roche Ltd. (1984a, pp. 26-30; 1984b, pp. 38-40).

62 See Hoffman-La Roche Ltd. (1984b, p. 4).

63 Particularly if, as noted above, many of these brands are supplied by licensees who own a license. See section 3.1 and footnote 48 above.

64 All of the seven drugs in our sample were purchased in Saskatchewan on the basis of an SOC. See Saskatchewan, Department of Health, Formulary, various issues.

65 In 1979 following the Bailey Report (Ontario, Ontario Drug Benefit Formulary Pricing Committee, 1978) the prices of thirty-six high volume drugs were listed in the Ontario formulary on the basis of package sizes of 1,000. This list included five of the seven drugs in our sample. In February 1984 downward price adjustments to the remaining two drugs were made in recognition of the fact that they were high volume. For details see Gordon (1984, pp. 16-17, and Appendix A, n.p.) Gorecki (1981, pp. 132-137), and Ontario, Ontario Drug Benefit Formulary Pricing Committee (1978, p. 8).

66 The median pricing rule described in Table 3 applied to all seven of the drugs in the sample, except for cimetidine 300 mg.

tabs, naproxen 250 mg. tabs, and propanolol 40 mg. tabs, where actual acquisition cost up to a maximum has been used since July 1, 1983. For details see Quebec, Régie de l'assurance-maladie du Québec (1984, p. 185). In the case of indomethacin 25 mg. caps there are only two suppliers in the period under consideration (Jan. 1, 1983 to June 30, 1984) and hence median pricing does not apply. In this case the province will pay for the brand dispensed as per the price quoted by the manufacturer whose brand is dispensed.

67 In Newfoundland the provincial formulary lists the package sizes which are used to derive the prices. For three of the four drugs in our sample which were interchangeable in Newfoundland in 1983, larger package sizes (500 or 1,000) were used. See Newfoundland, Newfoundland Interchangeable Drug Products Formulary (various issues) for details.

68 The province in question is Ontario. However, the gap between this list and actual acquisition cost has grown so large as to raise considerable concern in Ontario. See Porter et al (1971) Ontario, Ontario Drug Benefit Formulary Pricing Committee (1978) and Gordon (1984) and Gorecki (1981, pp. 132-137) for further details.

69 By implication we therefore omitted a number of factors. However, some of these would be common to all seven drugs, irrespective of the province under consideration, and hence should not influence our results at least in terms of an interprovincial comparison. For example, the length of time that a drug has been on the market might, as more doctors graduate using the proper or generic name in prescribing, lead to an increased use of licensee products and hence lower prices. However, a given drug is usually introduced for sale across Canada at about the same time. On the other hand, some factors which may be of importance do vary by province. Perhaps, potentially at least, the most important omitted factor is when the provincial formulary was first introduced. However, the evidence in Tables 6 and 7 throws some doubt on this suggestion. Newfoundland introduced its scheme in 1981 but by 1983 was more successful, in those cases where the province certified interchangeability, in promoting licensees market share than Saskatchewan. It may well be that the success of Ontario and Quebec in promoting licensee brands made it much easier for the other provinces to introduce their own schemes and be, depending upon the price/production selection rules etc., relatively successful in promoting lower priced brands. In other words, Ontario and Quebec performed a public service in that they generated spillovers and externalities.

70 See footnote 27 above concerning interchangeability. The influence concerning number of competitors is based upon data supplied by British Columbia's Pharmacare. See Appendix B below for details.

71 The exception is the assumption underlying Figure 1 that the demand curve is inelastic. This seems to command wide support. (See, for example, Walker, 1971, pp. 8-11.) What we have neglected, by the assumption that the demand elasticity is equal to zero, is the familiar welfare triangle. (See Scherer, 1980, pp. 459-464.) However, estimates of the size of this triangle are typically quite small, (Scherer, 1980, pp. 460-464) particularly when, in the present case there are huge gains to be realized because of the drop in price due to licensing. Since these latter gains are transfers from foreign shareholders to Canadian consumers and government they increase the welfare of Canadians.

72 See Gorecki (1981, pp. 126-147). However, this earlier work is not directly comparable with UNSAV, since index B (the complement of UNSAV) used published licensee prices on a provincial basis (to derive P_L) and made somewhat arbitrary adjustment of patentee prices of 20 per cent to derive P_P. Nevertheless in view of the data that was available this was the best that could have been done at the time.

73 Using the prices quoted in the July 1983 edition of the Saskatchewan Formulary.

74 A minor reason why Saskatchewan's SOC system does not reap the full benefits of compulsory licensing is the fact that the Formulary includes an 11 per cent mark-up for the wholesaling function, since the brand, of the tendered drug, that is awarded the SOC contract must be distributed to the pharmacist via a wholesaler. If this mark-up is removed from the SOC price then ACTSAV increases from 0.9195 to 0.9776. For further details on this mark-up and the mandatory use of wholesalers for SOC drugs, see Saskatchewan, Department of Health (1983, pp. 10-11) and Associated Health Planners (1983, p. 11).

75 For details see footnote 14 above.

76 See Associated Health Planners (1983, p. 4). In any event the same brands listed as interchangeable by Saskatchewan are usually listed also by Quebec and Ontario.

77 Saskatchewan Pharmaceutical Association (1984, p. 7). It should also be noted that of all the provincial drug plans Saskatchewan is viewed by the Pharmaceutical Manufacturers Association of Canada as the "worst legislated arrangement" (Associated Health Planners, 1983, p. 6).

78 This is similar to the practice in the U.K. of contacting those physicians which prescribe to a considerably greater extent than their colleagues. See U.K., Informal Working Group on Effective Prescribing (1982, pp. 2-4).

79 There is little controversy in this statement. See Porter et al (1971), Ontario, Ontario Drug Benefit Formulary Pricing Committee (1978), Gordon (1984), Gorecki (1981), Ontario College of Pharmacists (1984), Canadian Drug Manufacturers Association (1984b), and Archer (1984). The CDMA (1984b, n.p. in section titled 'Marketing Practices') summarizes the situation thus:

> Another factor in determining price for generic company products aside from positioning relative to the major brand is provision for a spread to benefit pharmacists in the ODB program. Price spread may be defined as the difference between the formulary price and a realistic single package price. Purchasing advantage may be defined as the difference between a realistic single package price and a quantity price. It became common practice for all companies to submit inflated prices for publication in the ODB book. Pharmacists were then charged a lower price, based on a so-called purchasing advantage but were able to bill the government at the higher price. They also tended to use the higher brand prices, where an even larger spread existed, as guides for price charged to the cash paying customers. The difference between reimbursed price for ODB patients/price charged to cash paying customers and manufacturers price to pharmacists became profit for the pharmacists and an important consideration in a pricing strategy.

80 Recall that P_A for Ontario is based upon the lowest price in the provincial formulary for each of the seven drugs in the sample and not the actual price paid by the provinical ODB. The difference will reflect a small number of no-substitution prescriptions. See Appendix B for full details.

81 Gordon (1984, p. 38, p. 44, and Appendix C, n.p.).

82 This is based upon Gordon (1984, various pages and Appendix C). Essentially there are no rules if the pharmacist decides not to product select.

83 Gordon (1984, pp. 43-44). Some additional information confirms this. Over the period July 1, 1982 to June 30, 1983 for the employees of several large automobile manufacturers insured through Green Shield, the mean market share held by the licensees for the seven drugs in our sample, was only 26.05, measured in quantity, and 21.69, measured in sales -- both well below the figures in Table 9 for the ODB programme. Futhermore, Green Shield reimbursed Ontario pharmacists for the price of the brand dispensed as per the Ontario formulary. For details see Green Shield Prepaid Services Inc. (1983, esp. Schedule II, n.p.).

84 Gordon (1984, p. 44).

85 Total non-ODB expenditure on drugs is estimated as follows: from Gordon (1984, p. 34) the total non-ODB expenditure on prescriptions (i.e., dispensing fee plus ingredient or drug cost) is $364,548,820; from Gordon (1984, Appendix C, n.p.) total dispensing fee costs in the non-ODB market is $160,500,000; the difference between the two figures is total drug cost in the non-ODB market. Some additional information would appear not to be inconsistent with this estimate. Green Shield, over the period July 1, 1982 to June 30, 1983, for the employees of several large automobile manufacturers insured through the firm, estimated that if all of the multisource prescriptions had been dispensed for the most expensive brand drug, costs would have increased 10.8 per cent. (See Green Shield Prepaid Services Inc. 1983, n.p., Schedule II, n.p.).

86 The procedure is as follows: Gordon (1984, pp. 43-44) says 60 per cent of all non-ODB prescriptions are either open (20 per cent) or brand name (40 per cent). If we assume that all non-ODB prescriptions have the same drug cost then those 60 per cent of prescriptions will be valued at 0.6 of $160.5 million = $96.3 million. We estimate that for these drugs the incremental payment due to non application of ODB rules is $22 million. Hence if these drugs were being purchased via ODB rules the cost would be $96.3 - $22 = $74.3 million. Therefore on average for multisource drugs, the non-ODB market pays 29.61 per cent extra per prescription for drug costs (i.e., $22/$74.3). If we assume that for the seven drugs in our sample that in the non-ODB market the P_A is 1.2961 the P_A in the ODB sector, then ACTSAV can be estimated for the whole province, where the weights attached to P_A in the ODB is 0.45 and 0.55 in the non-ODB market.

87 D.G. Archer (1984, p. 83).

88 Gordon (1984).

89 D.G. Archer (1984, pp. 86-88) for a statement by the Ministry of Health.

90 See Ontario, Ontario Drug Benefit Formulary Pricing Committee (1978), Gordon (1984, pp. 78-79), and Gorecki (1981, pp. 132-137).

91 Gordon (1984, p. 16).

92 Gordon (1984, Appendix A, n.p.).

93 If we had re-estimated ACTSAV for 1984 using P_P and P_L for 1984, rather than using P_P and P_L as derived in Appendix B, then ACTSAV would probably have been a little lower than 0.8085 -- the mean ratio, for our sample of seven drugs, of P_L, 1984 to P_L, 1983 was 0.9287.

94 D.G. Archer (1984, p. 85). The provincial Auditor considers only the ODB market. If the increase in the ODB dispensing fee results in an increase in the usual and customary fee of the pharmacist of an equivalent amount in the non-ODB market, with drug prices remaining much the same, then for Ontario as a whole, prescription costs may actually increase.

95 Gordon (1984, p. 16).

96 This is not to deny that the recommendations of Gordon (1984), if implemented, would result in lower drug prices for the ODB.

97 In order to derive this we took the median price as per the January, 1984 Quebec formulary and the February 1984 adjusted prices reported in the text for Ontario for the three drugs in Quebec which were reimbursed on an actual acquisition cost. Unfortunately, we did not have actual prices for Jan-June 1984, only Jan 1983-June 1984, so these approximations were necessary.

98 These are: methyldopa 250 mg. tabs; flurazepam 30 mg. caps; and allopurinol 100 mg. caps. Indomethacin 25 mg. caps because there were only two suppliers during the period Jan 1983-June 1984, was not priced using the median pricing rule, but on the basis of the price of the brand dispensed as per the manufacturer's price in the provincial formulary.

99 The Ontario scheme reimburses up to the lowest price among a group of interchangeable pharmaceutical products. The difference between the lowest and median price would appear to be small. Using the July-Dec 1983 Quebec formulary, these prices for the median priced drugs in footnote 98 are as follows:

	lowest price per tab or cap	median price per tab or cap	ratio
methyldopa 250 mg. tabs	0.0784	0.0940	0.8340
flurazepam 30 mg. caps	0.0710	0.0780	0.9103
allopurinol 100 mg. caps.	0.0391	0.0427	0.9157

Source: Quebec, Régie de l'assurance-maladie du Québec (1983, various pages).

For indomethacin only two prices are given, 0.1808 and 0.2206.

100 This was based upon the evidence presented in the paper and discussions with knowledgeable persons in the drug business, widely defined, in Quebec. Apparently no documentation like the Bailey Committee or Gordon Commission exists in Quebec.

101 Cimetidine 300 mg. tabs; naproxen 250 mg. tabs; and propranolol 40 mg. tabs.

102 Naproxen 250 mg. tabs were priced using the median pricing rule; there were only two brands of cimetidine 300 mg. tabs; and propranolol 40 mg. tabs the brand dispensed was reimbursed at the manufacturers price. See the Quebec formulary for Jan-June 1983.

103 See Quebec, Régie de l'assurance-maladie du Québec (1984, p. 185).

104 Unlike Ontario in February 1984 the Quebec provincial pharmacists were not given an increase in their dispensing fee, although one was requested.

105 For the brands concerned this price is as follows:

	July 1983	Jan 1984
	price per tab	
cimetidine 300 mg. tabs	0.1500	0.1500
naproxen 250 mg. tabs	0.2830	0.2830
propranolol 40 mg. tabs	0.0840	0.0840

Source: Quebec, Régie de l'assurance-maladie du Québec, Liste de médicaments, various issues.

A comparison of these prices indicates that they are above the corresponding ones for Ontario, for 1984, but below those for 1983. The Ontario prices are presented in the text above.

106 The price is supposed to be reduced to take into account any discounts, free gifts, etc. (See Quebec, Régie de l'assurance-maladie du Québec (1983, p. G.11, for details)). Furthermore some checks are conducted on the prices submitted for reimbursement.

107 See Gorecki (1981, pp. 137-142).

108 According to officials of the Newfoundland and Labrador Prescription Drug Programme, who made a special effort to get lower prices in this formulary. For the four drugs in our sample listed this is certainly the case:

	Jan. 1984	July 1984
	Price per tab or cap for lowest priced brand in formulary	
methydopa 250 mg tabs	0.0908	0.0635
cimetidine 300 mg tabs	0.1500	0.1112
allopurinol 100 mg tabs	0.0740	0.0432
propranolol 40 mg tabs	0.1050	0.0454

109 P_A was set equal to the lowest priced brand in the formulary for July-Dec. 1984 for each drug. According to officials of the plan there are very few no-substitution prescriptions.

110 Using the January, 1985 lowest priced brand for each drug in the formulary for the six listed as interchangeable as P_A and assuming ACTSAV=0 for the drug not listed as interchangeable, then the mean value of ACTSAV for the seven drugs is 0.6608. However, this estimate should be viewed with some caution because the P_L and P_P used to derive ACTSAV refer to 1983.

111 For example, given the mandatory price selection rules in Quebec and Ontario and the low incidence of no-substitution prescriptions in both provinces, there is little need for the provincial formulary to publish but a single price for a group of interchangeable pharmaceutical products. In Ontario a single price for multisource drugs was actually recommended by the Bailey Committee report in 1978 -- "The government should not produce a price book that can adversely influence drug costs for the remaining 75% [at that time] of the prescription market". (Ontario, Ontario Drug Benefit Formulary Pricing Committee, (1978, p. 14)). For a short while (the January-June 1979 formulary) this recommendation was actually implemented in Ontario. Apparently some legal requirements have to be met before such a change can take place. However, these have not been met to date. In Quebec, for a small, but important, number of drugs subject to actual acquisition cost only, a single price has been printed in the formulary since July, 1983.

112 However, it should be pointed out that for non-government prescriptions the dispensing fee is slightly higher. In 1984 the dispensing for government was $5.25 as compared with the market fee (i.e., the usual and customary) of $5.45.

113 See Nova Scotia, Health Services and Insurance Commission (1982, p. 4). A similar statement appears in other editions of the provincial formulary.

114 Since the estimates of ACTSAV for Nova Scotia relates to Oct.-Dec. 1983 the prices were obtained from the July-Dec. 1983 Nova Scotia, Prescription Drug Formulary.

115 Based on correspondence with the Nova Scotia Health Services and Insurance Commission. Apparently discussions are taking place between the Pharmacy Association and the Commission with a view to implementing such a scheme.

116 Like many other provinces the Nova Scotia provincial drug reimbursement plan does not apply to all of the province's population. (See Table 2) It seems likely, given that permissive

selection applies to both public and private parts of the province's drug markets, that pharmacists will follow much the same patterns of dispensing in the two markets.

117 It therefore seems likely that at least some of these benefits are captured by the pharmacits, who purchase in large lot sizes at lower than formulary prices. A similar comment also probably applies to Nova Scotia.

118 Memorandum to 'All Association Members' from 'Professional Services Committee' re 'Product Selection' dated Oct. 9, 1984, kindly supplied to the author by the New Brunswick Pharmacists' Association.

119 The mean value of ACTSAV for the three drugs listed as interchangeable was 0.0451, and 0.0000 for the four drugs for which interchangeability was not certified.

120 Letter from Charles G. Gallagher, Minister of Health, New Brunswick, to W.A. Kenndy, Secretary, Commission of Industry on the Pharmaceutical Industry, dated July 16, 1984. This is classified as Commission Brief No. 22.

121 For example, in 1979 an audit of 250 pharmacies resulted in recovery of overpayment from 12. See Mittee III, Vol. 4, No. 9, Sept. 14, 1979. This is the bulletin for Third Party Rx Programs published by the B.C. Pharmacists' Society. See also F. Archer (1984, p. 271) and Gordon (1984, pp. 68-71) on the B.C. system.

122 See Dunfield (1984) and Associated Health Planners (1983). Dunfield (1984) examines the prices of a small number of individual brands across Canada and not the mean price paid for all brands of a given drug. Hence, for example, while the price of brand x is high in one province little of it may be dispensed while in other provinces the brand may be 10 per cent lower, but substantial quantities dispensed. Associated Health Planners (1983) takes Saskatchewan quantities of given brands and then re-estimate total expenditure using other province's prices as weights.

123 No-substitution prescriptions would not appear to account for this difference according to officials in B.C.

124 Licensee prices are those for the two leading licensees who provided the price data discussed in Appendix B below. The price used was the weighted average of the price of these two firms.

125 British Columbia Pharmacists' Society (1984, pp. 7-8).

126 British Columbia Pharmacists' Society (1984, p. 8).

127 It seems likely that the value of ACTSAV is somewhat higher in the non-Pharmacare sector of the B.C. market because of greater product selection. The British Columbia Pharmacists' Society (1984, p. 7) comment,

> Analysis of Pharmacare payment data indicated that the professional prerogative of product selection was not exercised for third party paid prescriptions to the same extent as for self pay prescriptions. One reason for this was that there was no direct economic benefit to the patient financially protected by a third party agency. Another was the potential for conflict with the patient in dispensing a brand different from the one prescribed.

128 The non-government sector usually accepts the negotiated fee as a base and, as we have discussed above, will frequently charge a higher fee to the non-government sector. This latter fee is often referred to as the usual and customary or marketplace fee.

129 The ODB dispensing fee is taken from Gordon (1984, Appendix B, n.p.). The fee was $4.48 between January and March, $4.55, April to September, and $4.65, October to December. Assuming prescriptions are distributed equally throughout 1983 then the average dispensing fee would be $4.56. Note it is a maximum fee. The British Columbia fee is the weighted average fee charged across the seven drugs in our sample for 1983. Hence it is the actual fee.

130 Woods Gordon (1981a, p. 36) estimate that the increase in the number of prescription services (i.e., dispensing fees) for the ODB market with the 30 day rule compared to the dispense as written rule, when adjustments would be completed over a three year period, was 16.42 per cent. We applied this to the $4.56 to derive $5.31.

131 In view of this it is difficult to understand the necessity of the Ontario government increasing the ODB dispensing fee in February, 1984 by 0.35 in return for lower prices in the provincial formulary (Gordon, 1984, p. 16).

132 See Gorecki (1981, pp. 164-170).

133 First, in a number of instances, briefs to the Commission suggest that since such a large percentage of a firm's sales are subject to compulsory licensing it is difficult to see how prices can be raised on other drug products so that lost profits can be recouped. For example: Smith, Kline and French Canada Ltd. (1984, p. 11) state, "The financial viability of SK&F Canada Ltd. has been so threatened by the impact of compulsory licensing of our leading products (...comprising 87 per cent of sales)...; Ayerst McKenna and Harrison Inc. (1984, p. 4) state, "Virtually our entire major prescription product line faces competition from

licensed generics."; Miles Laboratories Ltd. (1984, p. 6) states that two products, "which account for 92 per cent of the sales volume of Miles fledging [sic] pharmaceutical division", had several compulsory licenses issued for them; Pfizer (1984, p. 3) state, "license applications are currently pending on our four major products which account for over 80 per cent of our pharmaceutical sales."; for Hoffman La Roche Ltd. (1984b, pp. 38-40) many of its major products have been affected by compulsory licensing; and Hoechst Canada Inc. (1984, p. 18) commented that the impact of generic brands of its "main product" (p. 12), furosemide, has been "an irreversible impact on the [Pharmaceutical] Division performance and threatened its viability" (p. 18).

Second, a number of the briefs to the Commission by firms for which licenses had been issued and in several cases were experiencing licensee competition, claimed that their prices in Canada were not high by international standards. For example: Merck Frosst Canada Inc. (1984, p. 51) state,

> Repeal of Section 41 would not lead to increased prices for pharmaceuticals. Provincial drug programs, which account for about 45% of sales, are able to choose the products they will or will not include in their plans; they therefore provide a built-in price-restraint mechanism. These provincial plans had not been established in 1969 when compulsory licensing under Section 41 was adopted. Furthermore, normal competitive market forces also act to restrain prices. For example, Merck Frosst prices in Canada were shown to be 16.5% lower than those in eight other countries at time of launch and in the middle of the group in 1984. In addition, the prices of Merck Frosst products with no compulsory licensing rose 3.1 percentage points a year more slowly from 1980 to 1984 than the prices of products with compulsory licensing...

Two of the seven drugs in our sample -- methyldopa and indomethacin -- are products for which Merck owns the patents; and Squibb Canada Inc. (1984, p. 6) commented concerning the introduction of a recent drug, which in 1982 had sales of over $2 million,

> We believe that the major pharmaceutical houses in Canada are responsible and reputable organizations who actively compete with one another thereby ensuring realistic market pricing structures. As an example, Squibb recently introduced a break-through product "Capoten" for the treatment of hypertension and congestive heart failure and in spite of its unique position and absence of generic competition in Canada, established a reasonable price structure as evidenced by a comparison with other international affiliates where patent protection exists:

Country	U.S. Currency	
Germany	$ 28.48	
United Kingdom	30.22	
Austria	28.48	per 25 mg.
Canada	22.05	tablets x 100
United States	21.85	
France	19.93	

Novopharm Ltd. currently has a license application before the Commissioner of Patents for this drug. Other firms entered opinions without any evidence. Bristol-Myers Pharmaceutical Group (1984, p. 21) felt,

> Undeniably, the most difficult issue in conjunction with the Patent Act changes is price. It is our judgement that, as a rule, Canadian pharmaceutical prices are not high in comparison to prices in many Western industrialized countries and, in fact, Canadian prices tend to be lower than in other countries. This is well supported by data submitted by the Pharmaceutical Manufacturers Association of Canada.

In contrast Wyeth Ltd. (1984, p. 9) stated,

> ...new products tend to be priced higher at introduciton and older products that have not yet been copied are increased in price at a faster rate than would normally be expected. The new products thereby become more attractive to generic copiers and the older products are priced out of the market - further reducing the opportunity to offset increased costs.

However, it is not clear that from Wyeth's view whether the earlier arrival of licensee competition will reduce or increase total drug expenditures. Hoffman La Roche Ltd. (1984a) assert that, "Although the prices of several specific medicines have decreased, the prices of other medicines, for which no licences have been sought, because of their lack of 'winner' potential, have increased". Finally, the industry association, PMAC (1984a, p. 52) finds the available evidence not at all decisive one way or the other, although somewhat later in their brief the PMAC state that an international price comparison generally showed that, "Canadian prices were generally within the middle to lower range of the six countries surveyed" (p. 80).

Nevertheless, one study (Kennett, 1982) is sometimes cited, (e.g., Canadian Medical Association, 1984, p. 8) as demonstrating that firms do indeed increase prices more quickly on single source drugs to compensate for losses on multisource drugs. In particular, Kennett (1982, p. 22) selects a class of drugs which are "...resistant to competitive forces because of physician and

consumer demand... Compulsory licenses where granted have little impact." For this group of drugs prices increased between January 1, 1979 to January 1, 1982 by 64.42 per cent (p. 26), well above a sample of licensed drugs, 5.44 per cent (p. 24) or the Consumer Price Index for prescribed medicines, 51.0 per cent (p. 23). Prices were based upon federal Department of Supply and Services National Individual Standing Offers, "basically manufacturers' catalogue prices for single units" (p. 22). From these results Kennett (1982, p. 23) concludes, that,

> ...if a company sustains a low profit margin on certain high volume products due to granting of compulsory licenses than [sic] it must invoke some compensatory mechanism to recoup the profit to remain viable ... The net effect of this pricing exercise is to neutralize the competitive pricing benefits from compulsory licenses.

However, based on Kennett's (1982) own evidence this conclusion seems inappropriate and unwarranted. Of the fifteen drugs in the group "resistant to competitive forces", five are sold by Parke-Davis Canada Inc. (1984, p. 14), which in its brief to the Commission states, "Parke-Davis was not immediately or significantly affected by compulsory licensing primarily because very few of its products were protected by patents or large enough volume to be attractive to generic firms." Hence Parke-Davis had no need for a compensatory mechanism. Another of the drugs listed by Kennett (1982, p. 26) as having been "resistant to competitive forces ..." is Indocid 25 mg. caps, for which the proper or generic name is indomethacin. This was one of our sample of seven licensed drugs and, as shown in Table 6, was listed in the January 1981 formularies for Saskatchewan, Ontario and Quebec as an interchangeable drug product. Indeed, in July 1981 in Saskatchewan the licensee won the SOC contract. However, Kennett (1982) offers no evidence that, "Compulsory licenses where granted have little impact ..." for this drug. A somewhat similar situation exists with respect to Metamucil, an OTC. In the January, 1979 and July, 1982, Ontario formularies this drug is listed as having three suppliers, two of which are generic firms -- ICN and Novopharm. (However, the drug concerned is not subject to compulsory licensing, the patent presumably having expired). No evidence is offered as to why ICN and Novopharm, provide inadequate competition. Furthermore three of the 15 drugs used by Kennett (1982) are one for which Merck owns the patent, and, as noted above, Merck claims, admittedly over 1980-1984, not 1979-1981, their non-licensed drugs rose in price more slowly than their licensed drugs. In sum, it would appear Kennett (1982) suffers from a number of important shortcoming which cast serious doubt, if not invalidate, the inferences drawn concerning the extent to which firms affected by compulsory licensing are able to raise prices on single source drugs.

See also Appendix B for some discussion of United States/Canada prices and Canada, Department of Consumer and Corporate Affairs (1983, pp. 42-43).

134 The figure was derived as a weighted average as follows:

	Weight (1)	ACTSAV (2)	(1).(2) (3)
Hospital market	0.20	1.00	0.2000
Retail market	0.80	-	-
Newfoundland	0.0277	0.2262	0.0063
Prince Edward Island	0.0048	0.2000	0.0010
Nova Scotia	0.0418	0.1854	0.0077
New Brunswick	0.0352	0.0193	0.0006
Quebec	0.1881	0.4405	0.0829
		(0.2946)	(0.0554)
Ontario	0.2676	0.4053	0.1085
		(0.2261)	(0.0605)
Manitoba	0.0255	0.5000	0.0128
Saskatchewan	0.0379	0.5213	0.0198
Alberta	0.0691	0.2000	0.0138
British Columbia	0.1006	0.5447	0.0547
Weighted average =	-	-	0.5081
			(0.4326)

The weights are estimated as follows: the 20:80 split between hospital and retail is taken from section 2.2.2 of the paper; with the weights attached to individual provincial retail market derived from Canada, Department of National Health and Welfare (1984, Tables 2, p. 32, Tables 20-29, pp. 50-59), for 1982. The values of ACTSAV are taken from Table 13, for Ontario, Newfoundland, British Columbia, Quebec, Nova Scotia, New Brunswick and Saskatchewan. In all cases these are the values of ACTSAV for the provincial government reimbursement programme and from our discussion seem reasonable approximations to ACTSAV for the non-government sector, except for Ontario and Quebec, where the figures in parenthesis are the estimates of ACTSAV for the whole of the Ontario and Quebec markets. For the hospital market we assume the HPI value of ACTSAV (i.e. 1.0000) is indicative of this sector -- clearly an assumption that will bias the weighted average upwards. Alberta, PEI and Manitoba were not in our sample, but based on the information in Tables 1, 2, 3 and 8 we inserted the estimates of ACTSAV, which are if anything on the high side. Hence the weighted average of ACTSAV is 0.5081, but if the estimates for Ontario and Quebec refer to the whole market then ACTSAV drops to 0.4326. Hence 50 per cent of the savings is perhaps a little generous.

135 The price paid by Green Shield is estimated from Green Shield Prepaid Services Inc. (1983, Schedule II, pp. 7-8) while the ODB price is that for the lowest brand, Novodipam in the January-June 1983 formulary. Reference to Table 10 shows that diazepam 5 mg. tabs was one of the 10 drugs which in 1983 held on average 89.8 per cent of the ODB market.

136 See discussion in section 4.3 under "Ontario".

137 See Davis (1983). As noted in Table 3 the Manitoba Formulary is for high volume multisource drugs.

138 California, Department of Finance (1977).

139 U.K., Committee of Public Accounts (1984).

140 There is some evidence that there are lower costs associated with larger pharmacy operations, hence making the choice of a "representative" pharmacy a difficult problem. Cady (1975, p. 40), for example, in his study of U.S. pharmacy operations concludes, "Significant scale economies exist over wide ranges of output in the retail prescription drug market". In Saskatchewan the dispensing fee paid by the province falls after the first 20,000 dispensed by a pharmacy, implying that costs are thought to fall with larger volumes.

141 See Economic Council of Canada (1981) and Skeoch et al, (1976) particularly the section titled, "Cost Justification and Economic Behaviour" (pp. 260-276).

142 Ontario, Ontario Drug Benefit Formulary Pricing Committee (1978, p. 14).

143 Gordon (1984, p. 88).

144 Based on discussions with various drug plan managers.

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Table 1

Provincial Product Selection Laws: A Summary, 1983

Province	Data Product Selection Legislation Introduced	Permissive or Mandatory[a]	Rules for Selection[b]	Determination of Cost	Determination of Interchangeability	Legal Protection for Pharmacist and physician
Alberta	1962	Permissive	None specified[c]	None specified	Pharmacist; no formulary	Not provided
British Columbia	1974	Permissive	Equal or lower priced than brand prescribed[d]	None specified	Pharmacist; no formulary	Not provided
Manitoba	1974	Permissive	Lowest price brand[e]	Formulary[e]	Formulary	No legal liability
New Brunswick	1975	Permissive	Equal to or less than the brand prescribed[f]	Pharmacist's usual and customary price[f]	Formulary	No legal liability
Newfoundland	1979	Permissive	Lowest price brand[g]	Formulary	Formulary	No legal liability
Nova Scotia	1983	Permissive	Equal to or less than the brand prescribed[h]	None specified	Formulary	Not provided
Ontario	1972	Permissive	Lower priced brand to that prescribed[i]	Lowest price brand in pharmacist's inventory[i]	Formulary	No legal liability
Prince Edward Island	No product selection legislation[m]					
Quebec	1974	Permissive	None specified[j]	None specified	Formulary[l]	Not provided
Saskatchewan	1971	Permissive	None specified[k]	None specified	Pharmacist (1971-1974); formulary (1975 onwards)	No legal liability

a All provinces do not allow product selection where the prescription is marked "no substitution" or in the case of Alberta "no equivalent" by the physician. In some instances the legislation specifies that the words "no substutition" be in the physician's handwriting. This reflects the provision of prescription pages by some drug firms with the words "no substitution" already printed across the prescription. In other words, the onus is on the physician to prevent selection.

b Emphasis added inall footnotes to entries in this column.

c "Where a prescription refers to a drug ... by a brand name [the pharmacist] ... may use a drug ... that is the generic or brand name equivalent of that named in the prescription...."

d "... a pharmacist may use an interchangeable pharmaceutical product where its price to the purchaser is no more than the price of the prescribed drug."

e "Every person who dispenses a prescription for a drug ... shall ... dispense an interchangeable pharmaceutical product other than the one prescribed ... [if it] is lower in cost than the drug prescribed." This is qualified by, "No person shall knowingly supply an interchangeable pharmaceutical product ... at a price in excess of the cost of the lowest priced interchangeable pharmaceutical product ... in the [formulary]." Hence the pharmacist, whether he product selects or not, cannot charge more than the lowest priced interchangeable pharmaceutical product in the formulary.

f Until June 29, 1983 the legislation read as follows: "Every person who dispenses a prescription may ... dispense an interchangeable pharmaceutical product other than the one prescribed, provided [it] ... is lower in cost than the drug prescribed." This is qualified by, "No person shall knowingly supply an interchangeable pharmaceutical product ... at a price in excess of the lowest price interchangeable pharmaceutical product in his inventory ..." Hence, once the pharmacist has decided to product select, no matter which brand is dispensed, the lowest priced brand in the pharmacist's inventory determines the maximum price that can be charged. On June 30, 1983 a new Pharmacy Act came into force. The new product selection wording read as follows: "Every person who dispenses a prescription may ... select and dispense an interchangeable pharmaceutical product other than the one prescribed, provided that [it] ... is listed as interchangeable in the New Brunswick Formulary." This provision was supplemented by a regulation under the Act, which read, "A licensed pharmacist ... shall not sell an interchangeable pharmaceutical product ... at a total price which is higher than the pharmacy's usual and customary price for either the product prescribed or the product dispensed." The text of the table refers to the rules in the second half of 1983.

g "... [the pharmacist] shall dispense a substitute drug other than the drug specifically prescribed where ... the drug to be substituted is cheaper than the drug prescribed ... or if he does not have the lowest price drug, dispense another drug listed in the Formulary as a substitute for the prescribed drug, at the price of the lowest priced substitute in the Formulary...."

h "Every person who dispenses a prescription may ... select and dispense an interchangeable pharmaceutical product other than the one prescribed ...."

i Language same as that of New Brunswick prior to June 30, 1983. See footnote f, above.

j "A pharmacist ... may substitute for the prescribed medication a medication whose generic name is the same ..."

k "... the pharmacist about to dispense a drug pursuant to the prescription may select and dispense an interchangeable pharmaceutical product other than the one prescribed."

l As mentioned in the text, the Quebec formulary only lists drugs of acceptable quality. Apparently because the Quebec government delisted a substantial number of drugs from the Formulary in the early 1980s, no references are made to the formulary in the actual Act, but nevertheless the Formulary is widely used for the products it lists.

m Legislation was proclaimed in January 1984, but has yet to take effect, because no interchangeable list has or is expected to be published in the near future.

Sources Provincial Pharmacy Acts, as well as rules and regulations made pursuant to such Acts. Information supplied by various provincial officials.

Table 2

The Coverage of Provincial Government Drug Reimbursement Programmes: A Summary, 1983

Provinces	Percentage of Population Covered[a] (% of Total Drug Bill)[b]	Class of Population Covered and any Patient Payment[c]	Date Original Programme Introduced and Extended to Present Coverage
Alberta	21 (n.a.)	welfare, nil; over 65, 20 per cent of the prescription; not covered under a private third party scheme or either of above two categories, $15.00 plus 20 per cent of the prescription cost in excess of this sum in a year	at least 1950's, present coverage since 1973
British Columbia	100 (45)	welfare and over 65, nil; others, $175 plus 20 per cent in excess of this sum for any calendar year per individual or family unit	1974, extended to "others" in 1977
Manitoba	100 (n.a.)	welfare, nil; over 65, $50 plus 20 per cent in excess of this sum for any calendar year per family unit; under 65, $75 plus 20 per cent in excess of this sum for any calendar year per family unit	1950's present coverage since 1975
New Brunswick	21 (n.a.)	welfare under 18, $1.00 payment per prescription; welfare over 18, $2.00 payment per prescription; over 65, $3.00 per prescription to a maximum of $30.00 per year; nursing home patients, nil	not known, present coverage since 1976
Newfoundland	22 (n.a.)	welfare, nil; over 65 and receiving Guaranteed Income Supplement, the dispensing fee	1960's, present coverage since early 1970's
Nova Scotia	13 (n.a.)	welfare; over 65; nil for both categories	not known, present coverage since 1976
Ontario	14 (45)	welfare; over 65; those under Family Benefit Act Extended Care Services and Homecare; nil for all categories	1974, present coverage since 1976
Prince Edward Island	11 (n.a.)	welfare; special disease states; nil for both categories	not known, present coverage since at least early 1970's
Quebec	19 (45)	welfare; over 65; nil for both groups	1972, present coverage since 1977
Saskatchewan	100 (100)	certain welfare recipients and special beneficiaries, nil; all others (including over 65) payment per prescription up to a maximum of $3.75 to Nov., then $3.95 in Dec.	1948, present coverage since 1975
Canada	33 (43)	----------	----------

a This refers to the total eligible population, not necessarily those receiving benefits. In Saskatchewan, for example, the total eligible population was 955,651 in 1982/83 but the number of beneficiaries was 661,151. (See Saskatchewan, Department of Health, 1983, Table III, p. 17 for details).

b Refers to the proportion of the province's total drug bill, at the retail level (i.e., excluding hospitals) accounted for by the Provincial Drug Reimbursement Programme. In several instances these are estimates and sometimes to per cent of prescriptions dispensed. Refers to 1983 or closest year.

c Often referred to as co-payment. Note that not all classes of population covered by the province are included in the table, only the major ones. For example, Nova Scotia has a drug assistance plan for diabetes insipidus patients.

Note A drug reimbursement programme is defined as a scheme whereby government pays in whole or in part the drug costs of a certain category or categories of the population.

Source Badgley and Smith (1979, pp. 79-91), Canada, Department of National Health and Welfare (1984), Gordon, (1984 various pages), Quebec, Régie de l'assurance-maladie du Québec (1984, p. 185) information provided by provincial and federal officials through the OUAD program, unpublished comparison survey of selected provincial government drug plans prepared by Ontario, Ministry of Health Drug Programs and Policy Group, March 1984 and an unpublished Description of Provincial Drug Reimbursement Programmes prepared by the federal Department of Consumer and Corporate Affairs.

Table 3

Drug Pricing Under Provincial Government Drug Reimbursement Programmes: A Summary, 1983[a]

Provinces	Drug Cost Definition for Reimbursement	Formulary (Date introduced)[i]	Maximum Supply per Prescription	Product Selection
Alberta	Cost to wholesaler plus 25 per cent	None	34 days, with exceptions up to 100 days	Permissive
British Columbia	Actual pharmacy cost[b]	None	100 days	Permissive
Manitoba	Drugs listed in formulary, price based on package size most commonly purchased by pharmacist; other drugs, price based on smallest package size available	Limited formulary for high selling multisource drugs (Jan. 1974)	None	Permissive (mandatory price selection)[c]
New Brunswick	Cost of smallest package size, usually 100's[j]	Limited formulary for high selling multisource drugs (Jan. 1977)	100 days	Permissive
Newfoundland	Cost of smallest package size, except for a small number of high selling multisource drugs where larger package sizes used	Limited formulary for high selling multisource drugs (May 1981)	None, but in practice 34 days or 120 doses, whichever is the greater	Permissive (mandatory price selection)[c]
Nova Scotia	cost of smallest package size, with some high volume drugs based on larger package sizes	Formulary (Jan. 1981)	34 days, but up to 100 days on instruction of physician	Permissive
Ontario	Cost to pharmacist of smaller package sizes (100's) except for a small number of high selling drugs where larger package size (1000's) used[d]	Formulary (Oct. 1970)	One month under normal cirumstances, not to exceed 6 months in any event	Permissive (mandatory price selection)[c]
Prince Edward Island	Actual acquisition cost to provincial dispensary[e]	None (n.a.)	60 days	Permissive[e]
Quebec	Cost of most popular selling package size purchased by pharmacist[f]	Formulary (July 1972)	None	Permissive (mandatory price selection)[c]
Saskatchewan	Provincial government tender system for high selling drugs (Standing Offer Contracts); for other drugs pharmacists' customary replacement cost	Formulary (Jan. 1975)	Six months[h]	Mandatory for Standing Offer Contract drugs and Permissive elsewhere (mandatory price selection in both instances)[c]

a Most of the provincial drug reimbursement programmes have had the same rules for drug reimbursement pharmacists since at least the mid-1970's to the present. In some instances, changes of some importance have taken place in the intervening period. For example, it was only in 1979 that Ontario moved to price high selling drugs based on larger package sizes, while Quebec moved to mandatory price selection in January 1982.

b B.C. government looks at average true acquisition cost in any given area or city and demands to see invoices if store claims reimbursement above local average price. There are only a small number of wholesalers in B.C. and the prices they charge to the pharmacist are also monitored by the government.

c See text for an explanation of this term.

d Pharmacist's costs from wholesaler, unless data has proven 50 per cent of a manufacturer's sales of these drug products in Ontario are via direct channels, in which case latter source is used. See Gordon (1984, Appendix A, n.p.) for the list of high volume drugs.

e For Prince Edward Island the provincial government operates a central dispensary from which drugs are distributed to the eligible categories mentioned in Table 2 above. In doing so the dispensary does make use of lower-priced licensee drug products. In this sense product selection is permissive.

f For a given drug Quebec will rank pharmacies in the province from high to low in terms of the number of (say) tablets dispensed over a six month period under the Quebec reimbursement plan; select the median store and estimate its average monthly sales of the drug; assume that the non-plan to plan ratio of sales is (say) 3:1, then scale up average monthly sales by 3 to derive the amount of a drug typically purchased for all of the store's customers; then select the package size (100, 500, 1000 etc.) closest to this average monthly sales figure to derive package size upon which government will reimbursement and place a price in the formulary. For a small number of high selling multisource drugs the formulary lists only one price for all brands of the given drug since July 1983. However, if the pharmacist purchases the drug for a lower price then the province would reimburse at the lower price only. If there are two or fewer brands median pricing does not apply and the province will pay for the brand dispensed as per the formulary price.

g For non S.O.C. drugs manufacturers provide firm price quotations for a six month period. Pharmacists must charge acquisition cost to a maximum of the price listed in the formulary for all drugs. Although the formulary price for low volume products may be based on smaller package sizes, pharmcists who buy these products in larger package sizes, at lower prices, must submit and are paid actual acquisiton cost. An allowance of 11 per cent for a wholesale mark-up is made in the published prices in the province's formulary on all drugs.

h For most drugs the pharmacist is entitled to one dispensing fee for each 34 day supply of medication. A pharmacist is entitled to one dispensing fee for each 100 day supply for certain maintenance drugs (thyroid, digoxin, anticonvulsants, oral hupoglycemics) and one dispensing fee for each two month supply of oral contraceptives.

i It might be noted that a formulary is sometimes introduced before product selection legislation (Table 1). This reflects early attempts by some provinces to provide information to pharmacists and physicians in order to influence prescribing and dispensing habits. Product selection legislation then followed, as for example in Ontario. For a further discussion see Gorecki (1981, pp. 11-12), particularly as it applies to Ontario and New Brunswick.

j Some drug firms supply direct to the pharmacist; others supply via a wholesaler, with a 20 per cent mark-up permitted by the wholsaler in the price he charges to the pharmacist.

Sources Information provided by various provincial and federal officials through the QUAD programme, as well an unpublished comparison of selected provincial government drug plans prepared by Ontario, Ministry of Health Drug, Programs and Policy Group, March 1984, various provincial formularies, and an unpublished Description of Provincial Drug Reimbursement Programmes prepared by the federal Department of Consumer and Corporate Affairs.

Table 4

Licensees, Licenses Issued and Worked Under Section 41(4) of the Patent Act: 1970-1983

Licensee Firm[a]	Drugs Licensed[b]	Licenses Worked and Drugs Currently on the Market[c]
Apotex Inc.	16	13
Frank W. Horner Ltd.	14	7
ICN Canada Ltd.	19	8
Novopharm Ltd.	36	24
Others[d]	96	13
Total	181	65

a As taken from the list of licenses granted by the Commissioner of Patents supplied to the author by the federal Department of Consumer and Corporate Affairs.

b As of December 31, 1983. No licenses were issued between June 1969 and December 1969. A license is dated by the year it was granted or issued by the Commissioner of Patents. As noted in the text we only refer to prescription drugs. See Appendix A and note 2 for details.

c "Worked" being defined as the licensee has marketed the drug for which the license was issued and that drug was on the market in December 1983.

d There were 29 other firms listed as having been granted at least one license between 1970 and 1983 by the Commissioner of Patents. In many cases mergers have taken place and/or the firm has gone out of business. For further details see Gorecki (1981, Table 4-2, p. 72).

Source List of licenses granted by the Commissioner of Patents supplied by the federal Department of Consumer and Corporate Affairs, various provincial formularies and the Canadian Drug Identification Code.

Table 5

Details of the Sample of Seven Multisource Drugs Used to Examine Pricing and Compulsory Licensing

Drug Dosage Form and Strength[a] (1)	Date Patentee First Introduced the Drug[b] (2)	Date First License Granted by Commissioner of Patents[c] (3)	Date Licensee First Introduced the Drug[d] (4)	Total Number of Licences Granted by Commissioner of Patents[e] (5)	Total Number of licensees to have Introduced the Drug[f] (6)
Central Nervous System Drugs					
indomethacin 25 mg. caps	1965 (1965)	1970	1980	4	1 (1)
flurazepam 30 mg. caps	1971 (1971)	1976	1980	4	4[g] (5)
naproxen 250 mg. tabs	1975 (1974)	1979	1982	3	2 (3)[h]
Cardiovascular Drugs					
propranolol 40 mg. tabs	1968 (1968)	1974	1980	3	2 (6)
methyldopa 250 mg. tabs	1963 (1963)	1970	1972	6	4 (7)
Gastrointestinal Drugs					
cimetidine 300 mg. tabs	1977	1981	1981	4	3 (4)
Unclassified Therapeutic Agents					
allopurinol 100 mg. tabs	1966 (1966)	1976	1978	6	4 (6)

a As noted in the text this is the most popular selling dosage form and strength.

b The date not in parenthesis refers to the year in which the patentee first marketed the specific dosage form and strength referred to in column (1). The date in parenthesis refers to the year in which the patentee first marketed any dosage form and stength of the drug. For example, Syntex Inc., the patent-owner of naproxen, first marketed the 125 mg. tab in 1974, with the 250 mg. tab following in 1975 and the 375 mg. tab in 1983.

c As per the list of licenses granted by the Commissioner of Patents supplied by the federal Department of Consumer and Corporate Affairs.

d As per the date of introduction on the print-out of current drugs on the market (i.e., Oct., 1984) supplied by Bureau of Non-Prescription Drugs, Department of National Health and Welfare.

e As of December 31, 1983.

f The number not in parenthesis refers to the total number of licensees to have introduced the licensed drug and be on the market by December 31, 1983 as per the lists referred to in footnotes c and d. The number in parenthesis refers to the total number of firms selling the licensed drug on and by December 31, 1983 excluding the patentee(s). The difference between the two columns in column (6) largely reflects the fact licensees will package and supply final dosage preparation for third-parties. However, in one instance a firm decided that the major patents on the drug had expired, with only minor process patents remaining extant. Hence the firm concerned decided not to apply for a license under section 41(4). To date the patentee has not brought a court action for patent infringement.

g One of the four licensees is Frank W. Horner Ltd. However, Horner sells flurazepam 30 mg. tabs not caps.

h In 1984 the patentee, Syntex Inc. marketed, through a subsidiary, Syncare, another brand of naproxen called Naxen, designed as a low priced brand to compete with the licensees. Naxen did not appear in the provincial formularies until July, 1984. The only other firm to adopt such a pricing/marketing strategy was the Upjohn Company of Canada Ltd. with respect to ibuprofen in 1983. See Upjohn (1984) for details.

Source Syntex (1984), Upjohn (1984), a list of licenses granted by the Commissioner of Patents supplied by the federal Department of Consumer and Corporate Affairs and a print-out of current drugs on the market (i.e., October, 1984) supplied by the Bureau of Non-Prescription Drugs, Department of National Health and Welfare.

Table 6

Licensee and Patentee Listings in Provincial Formularies for Six Provinces and Seven Drugs, 1970-1984

Drug, Brands Listed and Date First Listed	Province					
	Saskatchewan	Ontario	Quebec	New Brunswick	Nova Scotia	Newfoundland
Date Formulary Introduced	Jan. 1975	Oct. 1970	July 1972	Jan. 1977	Jan. 1981	May 1981
cimetidine 300 mg. tabs						
Total Number of Brands Listed						
January 1983	2	2	2	0	2	2
July 1983	3	4	4	0	4	3
January 1984	3	4	5	0	4	4
Date First Listed						
Patentee	Jan. 1979	Jan. 1978	Jan. 1978	Sept. 1984	Jan. 1983	July 1982
1st licensee	Jan. 1982	July 1982	Jan. 1982	Sept. 1984	Jan. 1983	July 1982
2nd licensee	July 1983	July 1983	July 1983	Sept. 1984	July 1983	July 1983
3rd licensee	July 1984	July 1983	July 1983	Sept. 1984	July 1983	Jan. 1984
indomethacin 25 mg. caps						
Total Number of Brands Listed						
January 1983	2	2	2	0	2	0
July 1983	2	2	2	0	2	0
January 1984	2	2	2	0	2	0
Date First Listed						
Patentee	Jan. 1975	Sept. 1974	n.a.	-	Jan. 1981	-
1st licensee	Jan. 1981	Jan. 1981	Jan. 1981	-	Jan. 1983	-
2nd licensee	-	-	-	-	-	-
3rd licensee	-	-	-	-	-	-
naproxen 250 mg. tabs						
Total Number of Brands Listed						
January 1983	3	3	3	0	3	0
July 1983	3	3	4	0	3	0
January 1984	3	3	4	0	3	0
Date First Listed						
Patentee	July 1976	July 1976	n.a.	Sept. 1984	Jan. 1983	-
1st licensee	Jan. 1983	Jan. 1983	Jan. 1983	Sept. 1984	Jan. 1983	-
2nd licensee	Jan. 1983	Jan. 1983	Jan. 1983	Sept. 1984	Jan. 1983	-
3rd licensee	-	-	July 1983	Sept. 1984	-	-
propranolol 40 mg. tabs						
Total Number of Brands Listed						
January 1983	3	4	5	0	3	3
July 1983	3	4	6	0	3	3
January 1984	3	4	6	0	3	3
Date First Listed						
Patentee	Jan. 1975	Sept. 1974	n.a.	Sept. 1984	Jan. 1983	July 1982
1st licensee	July 1981	Jan. 1981	July 1980	Sept. 1984	Jan. 1983	July 1982
2nd licensee	July 1982	Jan. 1982	Jan. 1981	Sept. 1984	Jan. 1983	July 1982
3rd licensee	July 1984	July 1982	Jan. 1981	-	-	-
methyldopa 250 mg. tabs						
Total Number of Brands Listed						
January 1983	4	5	8	4	4	4
July 1983	4	5	8	4	4	4
January 1984	4	5	6	4	4	4
Date First Listed						
Patentee	Jan. 1975	Sept. 1974	n.a.	Jan. 1977	Jan. 1981	May 1981
1st licensee	Jan. 1975	Sept. 1974	n.a.	Jan. 1977	Jan. 1981	May 1981
2nd licensee	Jan. 1977	Jan. 1977	n.a.	Jan. 1978	Jan. 1981	May 1981
3rd licensee	July 1979	Jan. 1978	n.a.	July 1981	Jan. 1983	May 1981
flurazepam 30 mg. caps						
Total Number of Brands Listed						
January 1983	3	4	5	4	3	0
July 1983	3	4	6	4	3	0
January 1984	3	4	6	4	4	0
Date First Listed						
Patentee	Jan. 1975	Sept. 1974	n.a.	Jan. 1983	Jan. 1983	-
1st licensee	Jan. 1981	Jan. 1981	Jan. 1981	Jan. 1983	Jan. 1983	-
2nd licensee	July 1981	Jan. 1982	Jan. 1981	Jan. 1983	Jan. 1983	-
3rd licensee	-	July 1982	July 1981	Jan. 1983	Jan. 1984	-
allopurinol 100 mg. tabs						
Total Number of Brands Listed						
January 1983	5	5	7	4	4	6
July 1983	5	5	7	4	4	6
January 1984	5	5	7	4	5	6
Date First Listed						
Patentee	Jan. 1975	Sept. 1974	n.a.	Jan. 1980	Jan. 1983	May 1981
1st licensee	July 1978	July 1978	July 1978	Jan. 1980	Jan. 1983	May 1981
2nd licensee	Jan. 1980	July 1979	Jan. 1979	July 1981	Jan. 1983	May 1981
3rd licensee	July 1981	July 1981	July 1980	Jan. 1983	Jan. 1983	May 1981

a The use of licensee in this table refers to either a licensee selling the drug under its own name and brand or a third-party purchasing the final packaged drug, but using its own brand. This latter practice occurs particularly in Ontario (e.g., Drug Trading Co. Ltd.) and Quebec (e.g., Laboratoire Pro Doc Limitée, and Laboratoire Medic Limitée). See note f to table 5.

b The patentee for naproxen, Syntex Inc. marketed through a subsidiary, Syncare, another brand of naproxen, Naxen, designed as a low priced brand to compete with the licensees. It was included in the Saskatchewan, Quebec, New Brunswick and Ontario formularies in July 1984.

Note For Quebec in a number of instances, n.a. appears indicating that we were unable to obtain provincial formularies for the early and mid-1970s. However, previous work (Gorecki (1981, pp. 77-83) indicated that drugs were listed in the Quebec formulary at or before the Ontario listing.

Source Provincial government formularies, various issues.

Table 7

The Importance of a Formulary Listing as Interchangeable in Provinces with Differing Product and Price Selection Rules for Seven Multisource Drugs, 1983

Sample of Drugs	Newfoundland	Saskatchewan
	Average Licensee Market Share[c]	
Listed in Newfoundland Formulary in 1983[a] as		
Not Interchangeable(3)	9.7	(59.2
Interchangeable (4)	76.0	Interchangeable((57.2
	New Brunswick	Nova Scotia
	Average Licensee Market Share[c]	
Listed in New Brunswick Formulary in 1983[b] as		
Not Interchangeable (4)	3.2	(13.9
Interchangeable (3)	5.1	Interchangeable((5.8

a All of the drugs were listed in Saskatchewan as interchangeable. See Table 6 for those drugs of the seven multisource drugs which were or were not listed as interchangeable for Newfoundland. The number in each category is listed in parenthesis. Data for Newfoundland refers to the six months ending September 30, 1983, and Saskatchewan to October-December, 1983.

b All of the drugs were listed in Nova Scotia as interchangeable. See Table 6 for those drugs of the seven multisource drugs which were or were not listed as interchangeable for New Brunswick. The number in each category is listed in parenthesis. Data for New Brunswick refer to September 28, 1983 to March 23, 1984 and for Nova Scotia, October-December, 1983.

c Measured in quantity (i.e., number of caps or tabs).

Source Various provincial formularies and data supplied by the provincial drug plans in New Brunswick, Newfoundland, Nova Scotia and Saskatchewan.

Table 8

Price and Product Selection Rules Under Selected[a] Provincial Drug Reimbursement Programmes: 1983

Price Selection	Product Selection	
	Permissive	Mandatory
None	pharmacist can select at own discretion[d]: British Columbia, New Brunswick; and Nova Scotia	-
Mandatory	must charge up to a maximum price; irrespective of brand dispensed; Ontario and Newfoundland (maximum price = lowest); Quebec[c] (maximum price = median price)	must dispense a particular brand at a particular price:[b] Saskatchewan

a We exclude Alberta (which would be classified with British Columbia, Nova Scotia, and New Brunswick) and Manitoba (which would be classified with Ontario and Newfoundland).

b This is the rule for SOC drugs. All seven multisource drugs in the sample are SOC.

c For: cimetidine, 300 mg. tabs; naproxen, 250 mg. tabs; and propranolol, 40 mg. tabs in July-December 1983 and all of 1984 Quebec set a single maximum price up to which it would reimburse, no matter which brand was dispensed. However, if the pharmacist purchased the drug for a lower price then the province would reimburse at this lower price. For indomethacin 25 mg. caps there are only two suppliers in Quebec and hence median pricing does not apply. The province will pay for the brand dispensed.

d However, <u>if</u> the pharmacist decides to product select then usually he is required to select a brand which is equal to or lower in price than the brand prescribed.

Source Table 3 above and various provincial formularies.

Table 9

Average Licensee Market Share for Seven Licensed Drugs,[a] Selected Dosage Forms and Strengths, Various Provincial Government Drug Reimbursement Markets: 1983

Province (period to which market share refers)	Average Market Share of Licensees[b] (standard deviation)	
	Measured in Units of Output (i.e., quantity)[c]	Measured in Sales
British Columbia (1983)	30.58 (9.39)	19.89 (6.76)
Saskatchewan (Oct-Dec, 1983)	58.01 (6.11)	36.42 (9.46)
Ontario (1983)	78.20 (n.a.)	77.03 (n.a.)
Quebec (1983 and Jan-June, 1984)	54.71 (n.a.)	47.17 (n.a.)
New Brunswick (Sept. 28, 1983 - March 23, 1984)	4.00 (3.17)	3.73 (3.08)
Nova Scotia (Oct-Dec, 1983)	10.44 (6.20)	8.26 (4.91)
Newfoundland (April-Sept, 1983)	47.59 (35.81)	43.65 (34.29)

a See Table 5 for listing of seven licensed drugs, and the dosage form and strength selected.

b For all provinces except Quebec, the provincial drug reimbursement programmes provided market share data. However, for Quebec averages were provided to the author which did not exactly match the seven drugs in Table 5. Hence some adjustments were made to derive the percentages for this province. It is believed that the averages for Quebec are probably accurate to within a couple of percentage points or so.

c Usually number of caps or tabs. In some instances prescriptions.

Source The provincial drug reimbursement programmes for British Columbia, Saskatchewan, Ontario, Quebec, New Brunswick, Nova Scotia, and Newfoundland.

Table 10

Average Licensee Market Share for Ten Licensed Drugs, Selected Dosage Forms and Strengths,[a] Various Markets, 1976-1983

Hospital		Retail[b]					
Hospital Purchasing Inc., Toronto		Ontario (Ontario Drug Benefit)		Quebec (Programme de medicaments du Quebec)		Saskatchewan (Saskatchewan Prescription Drug Plan)	
Year[c]	%	Year[d]	%	Year[g]	%	Year[e]	%
Market Share Measured in Units of Output (i.e., quantity							
1978/79	62.5	1977	55.0	1976	9.4	1976	26.9
1980/81	66.7	1980	64.4	1978	12.3	1979	61.2
1983/84	80.0	1983	89.8	1983/84	78.9	1983	69.2
1984/85	90.0						
Market Share Measured in Sales (i.e., prices)							
1978/79	62.5[f]	1977	54.2	1976	8.4	1976	19.9
1980/81	66.7[f]	1980	62.1	1978	10.6	1979	37.3
1983/84	80.0[h]	1983	83.4	1983/84	70.6	1983	38.3
1984/85	90.0[h]						

a The licensed drugs and the high selling dosage form and strength selected, covering a variety of therapeutic categories, were as follows: amitriptyline 25 mg. tabs.; diazepam 5 mg. tabs.; clofibrate 500 mg. caps.; furosemide 40 mg. tabs; methyldopa 250 mg. tabs; ampicillin 250 mg. caps; amoxicillin 250 mg. caps.; cloxacillin 250 mg. caps.; erythromycin estolate 25 mg./ml. susp.; and chlorpropamide 250 mg. tabs.

b In all instances the retail market refers to provincial government drug reimbursement programmes. For full details see Table 2 above for situation in 1983 and Table 1-2 in Gorecki (1981, p. 2) for situation in 1980.

c Should be read as year ending June, although this did vary be drug somewhat.

d Refers to May of 1977 and 1980, and Jan-Dec, 1983.

e Refers to the first quarter of 1976 and 1979, and last quarter of 1983.

f For one of the ten drugs HPI did not let a contract in either year, while for another, information was not available on the firm which was awarded the contract in 1978/79.

g Refers to Jan-Dec 1976, 1978, and Jan 1983 to June 1984.

h In 1983/84 and 1984/85 HPI let contracts on all 10 drugs.

Source Information provided by Hospital Purchasing Inc., Ontario Drug Benefit, Programme de medicaments du Quebec, and the Saskatchewan Prescription Drug Plan.

Table 11

Licensee Market Share for Selected Licensed Drugs for Quebec,[a] Measured in Terms of Prescriptions, 1981 and 1982

Drug[b]	Market Share of Licensees	
	1981 (Oct-Dec)	1982 (Jan-Mar)
allopurinol	14.91	50.67
amitriptyline	28.05	60.10
methyldopa	14.25	47.51
chlorthalidone	16.83	52.46
thiordazine	29.86	66.87
furosemide	24.04	63.04
flurazepam	2.97	42.39
Mean	18.70	54.72

a Based on all sections of Quebec retail market, not just the provincial drug reimbursement programme.

b From the data source it would appear that the number of prescriptions per drug refer to all prescriptions for the drug, irrespective of the dosage form and strength.

Source Pharmaceutical Manufacturing Association of Canada (1982, pp. 66-76).

Table 12

The Ranking[a] of the Influence of Four Factors on the Mean Price Level Paid by Seven Provincial Drug Reimbursement Programmes for Seven Drugs,[b] 1983.

Province	Factor				Overall Ranking
	Interchange-ability	Price/Product Selection Rules	Number of Competitors	Cost Determination	
British Columbia	? (1 or 3)	3	? (1)	2	3
Saskatchewan	1	1	1	1	1
Ontario	1	2	1	3	2
Quebec	1	2	1	3	2
Nova Scotia	1	3	1	3	3
New Brunswick	2	3	2	4	4
Newfoundland	2	2	2	3	3

a The higher the rank the greater the expected impact of that factor in lowering the mean price paid by the province for the sample of drugs.

b See Table 5 for details of the sample of seven drugs.

Source See text.

Table 13

The Potential, Actual, and Still to be Realized Savings Due to Compulsory Licensing and Associated Provincial Government Reimbursement Programmes for Seven Multisource Drugs, for Seven Provincial Drug Reimbursement Programmes, 1983[a]

Province	POTSAV[b]	ACTSAV[b]	UNSAV[b]
	Average[c] (Standard Deviation)		
British Columbia	0.6538 (0.094)	0.5447 (0.103)	0.4553 (0.103)
Saskatchewan	0.6538 (0.094)	0.5213 (0.062)	0.4787 (0.062)
Ontario	0.6538 (0.094)	0.4053 (0.144)	0.5947 (0.144)
Quebec	0.6538 (0.094)	0.4405 (0.236)	0.5595 (0.236)
New Brunswick	0.6538 (0.094)	0.0193 (0.031)	0.9807 (0.031)
Nova Scotia	0.6538 (0.094)	0.1854 (0.181)	0.8146 (0.181)
Newfoundland	0.6538 (0.094)	0.2262 (0.238)	0.7738 (0.238)

a See Table 9 for period to which index applies for a particular province

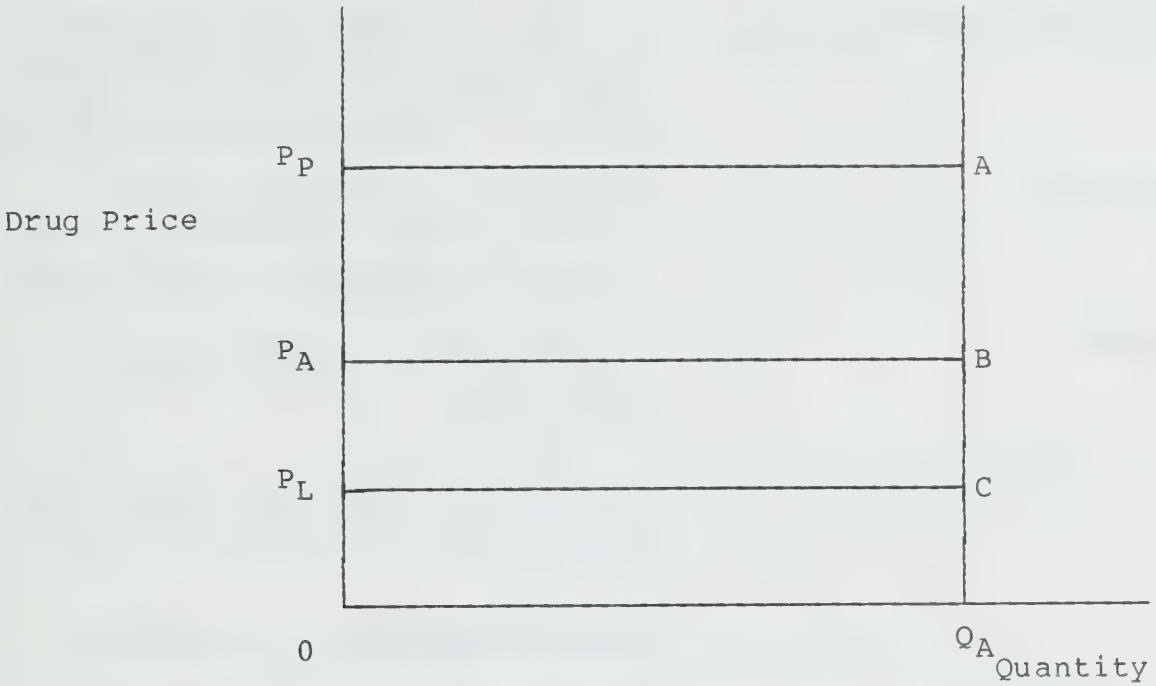
b These are defined in the text.

c Unweighted average of the index across seven drugs. See Table 5 for full details of sample of drugs.

Source Data provided by various provincial governments, licensees and the Saskatchewan Formulary, various issues.

Figure 1

Savings, Actual, Potential and Still to be Realized Due to Compulsory Licensing and Associated Provincial Government Programmes



P_P = patentee price in the absence of compulsory licensing and associated provincial drug programmes

P_A = actual price paid by provincial drug reimbursement programme

P_L = price which would be charged if the industry were perfectly competitive

Q_A = actual amount reimbursed by the provincial government drug reimbursement programme

GLOSSARY OF TERMS

Bailey Committee	Ontario Drug Benefit Formulary Pricing Committee.
Brand name prescription	The physician writes a specific brand name (e.g., Valium) but the words "no-substitution" do not appear on the the prescription.
Commission	Commission of Inquiry on the Pharmaceutical Industry.
HPI	Hospital Purchasing Incorporated.
licensee	A firm that has taken out a compulsory license(s) under the Patent Act.
No-substitution prescription	The physician writes a specific brand name (e.g., Valium) and the words "no-substitution" on the prescription.
ODB	Ontario Drug Benefit Programme.
Open prescription	The physician writes the generic or proper name of the drug. For example, instead of Valium (i.e., a brand name), the physician writes diazepam.
Patentee	A firm that owns a patent(s) for which a compulsory license has been issued by the Commissioner of Patents.
SOC	Standing Offer Contract.

APPENDIX A

DRUGS FOR WHICH COMPULSORY LICENSES HAVE BEEN ISSUED BY THE COMMISSIONER OF PATENTS: 1970-1983

The Commissioner of Patents issued licences for 70 drugs over the period 1970 to 1983. (In 1984 a large number of licence applications remain before the commissioner, which have not been granted as yet. In a number of instances patentees are bringing court cases). Of the 70, 58 were classified as prescription drugs for human use and these are presented in Table A-1. Drugs classified to Schedule F of the federal Food and Drugs Act are prescription drugs. Regulation C.01. 041(1) pursuant to that Act states,

> no person shall sell a substance containing a drug listed or described in Schedule F to the Regulations ... unless he has received a written or verbal prescription therefore.

Thus Schedule F drugs was used to determine whether a drug was prescription or non-prescription, in consultation with officials of the Department of National Health and Welfare.[1] The remaining twelve drugs consisted of three for veterinary purposes (i.e., acepromazine maleate, tetramisole, and trichlormethiazide), six human ethical non-prescription (i.e., bisacodyl, lidocaine, tolnaftate, nylidrin, pyrantel pamoate and cyproheptadine), two drugs for human use, which were not on sale to the public but used predominantly in hospitals for various purposes (i.e., diatrizoate and halothane) and, finally, one vaccine (i.e., anti-rabies).

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1 Provinces can, however, classify a non-prescription drug as a prescription drug, but not vice-versa.

TABLE A-1

Human Prescription Drugs for Which Compulsory Licences Have Been Issued, Classified by Pharmacologic - Therapeutic Classification, 1970-1983

Central Nervous System

amitriptyline
chlordiazepoxide
chlordiazepoxide/clidinium bromide
chlorpromazine
clorazepate dipotassium
diazepam
diethylpropion hydrochloride
flurazepam
glutethimide
haloperidol
hydroxyzine
ibuprofen
imipramine
indomethacin
ketoprofen
lorazepam
methotrimeprazine
methylphenidate
naproxen
oxyphenbutazone
oxazepam
perphenazine
primidone
thioridazine
trifluoperazine

Anti-infectives

ampicillin
amoxicillin
benzathine (penicillin G.)
cephalexin monohydrate
cloxacillin
erythromycin estolate
ethambutol
gentamicin sulfate
metronidazole
rifampin
oxytetracycline
trimethoprim/sulfamethoxazole

Cardiovascular

chlorothiazide
chlorthalidone
clofibrate
furosemide
hydrochlorothiazide
methyldopa
metoprolol tartrate
propranolol
spironolactone
triamterene

Hormones & Substitutes

chlorpropamide
hydrocortisone sodium succinate
phenformin

Skin and Mucous Membrane

betamethasone-17-valerate
fluocinolone acetonide
triamcinolone acetonide

Autonomic Agents

salbutamol

Unclassified Therapeutic

allopurinol

Gastrointestinal

cimetidine
diphenoxylate hydrochloride
furazolidone

Note: In a number of instances the salts are also indicated and a drug may be listed under more than one pharmacologic - therapeutic classification

Source: Schedule F to the Food and Drugs Act, advice from officials of the Department of National Health and Welfare, and a list of licences issued supplied by the federal Department of Consumer and Corporate Affairs

APPENDIX B

DATA SOURCES AND METHODS

B.1 Introduction

The purpose of this Appendix is to provide a description of the data provided by each of the seven provincial drug reimbursemnt programmes from which data was both sort and received as well as Hospital Purchasing Incorporated. This is to be found in section B.2. The derivation of the licensee and patentee price used in section IV of the paper is presented in sections B.3 and B.4, respectively, while section B.5 carefully specifies some of the important assumptions and possible limitations of the three indices presented in Table 13 of the text.

B.2 Provincial and Hospital Data[1]

The provincial data was collected by T. Brogan of the Bureau of Policy Co-ordination of the federal Department of Consumer and Corporate Affairs as part of a larger exercise of gathering data on drug costs. In each case the relevant provincial authorities were contacted for permission to use this data. Such consent was granted by Saskatchewan, British Columbia, New Brunswick, Nova Scotia, and Newfoundland. In the case of Quebec the provincial authorities were approached separately because the data required had not been collected by the Bureau of Policy Co-ordination. Ontario was unable to grant permission but did provide some information directly. Finally, the author contacted HPI directly

and was granted access to their purchasing records. In all cases data was provided on the understanding that prices and sales relating to individual brands would not be released in this report. Hence the use of averages in, for example, Tables 9, 10, and 13.

British Columbia. The B.C. provincial drug remimbursement programme, Pharmacare, provided, for the calendar year 1983, for all brands of high volume, both single and multisource, drugs, by dosage form and strength:[2] total number of prescriptions dispensed; total ingredient cost; total quantity (i.e., number of caps or tabs); and average dispensing fee. Hence these data would be provided for all brands of (say) cimetidine 300 mg tabs.

Saskatchewan. The Saskatchewan Prescription Drug Plan for the drugs in Tables 9 and 10 and a limited number of other drugs[3] for Oct-Dec 1983 provided for the dosage forms and strength selected for each drug and for each brand:[4] total number of prescriptions; total units (i.e., tabs or caps); and total drug or ingredient cost. Hence, like B.C., data is provided for all brands of (say) cimetidine 300 mg tabs.

Ontario. The Ontario Drug Benefit Programme provided: the mean market share percentages used as the basis for the Ontario numbers in Tables 9 and 10 for 1983; and also for 1983 the total quantity dispensed for all brands, taken together, of each of the dosage

forms and strengths of the seven multisource drugs listed in Table 5. In other words, for example, for cimetidine 300 mg. tabs only one quantity is provided, which is the sum of the quantity of Tagamet, Peptol, etc. of this dosage form and strength reimbursed for by ODB. However, for allopurinol the quantity referred to was the 300 mg. tab. The ODB was unable to supply any additional information such as total ingredient cost for the multisource drugs. Hence P_A for Ontario for 1983 is the average of the lowest priced interchangeable pharmaceutical product, for each drug dosage form and strength in the seven drug sample, in the Jan-June and July-Dec forumularies. As Tables 9 and 10 show the licensees were able to capture a very substantial share of the Ontario market so this procedure should not seriously distort the results reported in Table 13. In any event the direction of the bias is upward for ACTSAV and hence downward for UNSAV, with POTSAV being unaffected.

Quebec. The Régie de l'assurance-maladie du Québec provided: the mean market share percentages included in Tables 9 and 10 for Quebec for January 1983 to June 1984; and the number of prescriptions dispensed, the total quantity (i.e., tabs, caps) and total ingredient cost for all brands, taken together, of each of the dosage forms and strengths of the seven multisource drugs listed in Table 5. It is the policy of the Régie de l'assurance-maladie du Québec not to provide data that refers to an individual

manufacturer. Hence market share data for individual brands of the patentee or licensee(s) is not available.

New Brunswick. The New Brunswick Prescription Drug Plan provided, for the period September 28, 1983 to March 23, 1984 for all brands of all dosage forms and strengths of each drug covered by the plan: total number of prescriptions; most common quantity per prescription; amount billed (includes dispensing fee); copayment; and amount billed. To estimate total ingredient cost the following procedure had to be adopted: amount paid plus copayment, less the $5.55 (the dispensing fee) multiplied by the number of prescriptions. It is assumed that phamacists always charge the maximum fee -- $5.55.

Nova Scotia. The Nova Scotia Health Services and Insurance Commission provided for the period Oct 1, 1983 to December 31, 1983 for all brands of all dosage forms and strengths of each drug covered by the Commission: total quantity; total number of prescriptions; total drug or ingredient cost; and total dispensing fee.

Newfoundland. The Department of Health provided, for the six month period to September 30, 1983, for the seven drugs in the sample the average price and number of units paid for by the provinces's drug reimbursement programme. In some instances all

dosage forms and strengths were referred to, in others just the sample dosage form and strength.

Hospital Purchasing Incorporated. HPI provided the author with access to documents which presented details of the 1984/85 tendering process and the firm which was awarded the 1983/84 contract. The details included: prices for various package sizes; total amount for which the tender was awarded (i.e., 500,000 caps or whatever); and identity of the firm which was awarded the contract.

B.3 The Licensee Price

In order to evaluate the impact of compulsory licensing and associated provincial government programmes we need the price at which the drug would be supplied were there essentially no patent protection or product differentiation between brands of the same drug or interchangeable pharmaceutical product. In other words, we need the price which would be established were the market for a particular drug perfectly competititve. Under such conditions all brands would sell for a single price, equal to the marginal cost of production. However, as the main text of the paper makes clear the drug industry cannot be characterized, in general terms, as perfectly competitive. Hence some proxies and assumptions are required in order to generate P_L.

We assume that the licensee price can be considered a good indicator of the price that would be charged in a competitive market. Several reasons suggest that this is a reasonable assumption. First, the conditions under which the licensees supply the major provinces and many of the smaller ones would seem to be very competitive, with any rents to be earned frequently going to the pharmacist. Second, the leading licensees (see Table 4) are all well established firms with substantial sales:

Licensee Firm	Date Established (Manufacturing in Canada)	1983 Total Sales ($ Million)
Apotex Inc.	1974 (1974)	20-30
Frank W. Horner Ltd.	1912 (1912)	30-40
ICN Canada Ltd.	1956 (1971)	10-20
Novopharm Ltd.	1965 (1969)	50+

Source: Drug Merchandising (1984) and Gorecki (1981, Table 4-2, p. 72.

Hence their prices are not reflective of marginal operators entering the market for the first time and perhaps making a mistake in pricing and exiting. Third, since we are taking average prices we are implicitly assuming that the cost curve is horizontal, so that MC = AC. This is the small country assumption -- Canada's demand for the raw material or active ingredient is small

enough in relation to world demand that the price is a constant -- combined with the view that entry is quite easy so that should price exceed marginal cost entry will take place to ensure the equality between MC and price. Apotex Inc., for example, entered in 1974 and has been very successful.

A problem arises over which licensee price to use and to verify its veracity. Two leading licensees were contacted, separately, and requested to supply actual selling prices for 1983. One licensee supplied actual average prices for the various drugs in our sample while the other licensee provided his price list for larger customers.[5] Both related, as requested to 1983, although some information was provided for earlier and later years. We compared the prices from the two sources by taking the ratio of licensee A's prices to licensee B's prices for the seven drugs used to estimate ACTSAV, UNSAV and POTSAV in Table 13. The results were as follows: mean, 1.0184; standard deviation, 0.0349; minimum, 0.9634; and maximum, 1.0605. Furthermore, the ratio was not significantly different from unity, with a t-value of 0.53.[6]

We took the analysis a step further by comparing licensee A and B prices, as supplied to the author, with the price reimbursed under the B.C. Pharmacare plan for these two licensees for 1983. B.C. was selected because it is frequently considered to come

closest to actual acquisition cost. The results were similar for both A and B so we report only the ratio the price B.C. Pharmacare reimbursed for licensee A to licensee A's price as supplied to the author. Across our sample of seven drugs the results were as follows: mean, 1.1586; standard deviation, 0.0863; minimum, 1.0906; and maximum, 1.3291. The ratio was not significantly different from unity at 0.05 but was at .10

Finally, we undertook the same exercise, but instead compared licensee A and B prices, as supplied to the author, with the published price of the firm which was awarded the SOC contract in Saskatchewan,[7] whether or not it was licensee A or B. In July-Dec 1983 the ratio of the SOC price to licensee B's price was as follows: mean, 1.0465; standard deviation, 0.0456; minimum, 0.9798; and maximum, 1.117. The ratio was not significantly from unity, with a t-value of 1.02. In Jan-June, 1983 the same ratio was not significantly from unity either, but the mean and variance were much greater: mean, 1.2382; standard deviation, 0.2521; minimum, 1.0111; and maximum, 1.7663.

These discussions give us considerable confidence in the prices supplied to the author by the two licensees. Given their closeness it matters little which we use. After some consideration it was decided to use licensee B since data was available for a greater sample, since initially, at least, we had

anticipated estimating ACTSAV, etc. for a larger sample of drugs. However time and resource constraints meant this was not completed.

B.4 The Patentee Price

The patentee price should be that price the patentee would charge if there was no compulsory licensing and associated government programmes. However, we do have compulsory licensing and associated government programmes. Nevertheless, there exists within Canada several markets where the patentee is able to charge a price that is unlikely to be affected by the various government programmes outlined above. In our discussion in section III two such markets were identified: the no-substitution section of the Saskatchewan market and the New Brunswick provincial drug programme. We estimated some comparative ratios across and within provinces to examine the reliability and usefulness of the use of Saskatchewan and New Brunswick data.

We calculated the ratio of the patentee's price as listed in the Saskatchewan Formulary for July-December 1983 to the actual price paid by the Saskatchewan Prescription Drug Plan for the patentee's brand in October-December 1983.[8] We would expect that since such prescriptions are no-substitution the patentee would have little

reason to discount from the listed price. This indeed appears to be the case. The statistics of the list price to the actual price paid by the Saskatchewan Prescription Drug Plan for the patentee brand of the seven drugs in our sample is as follows: mean, 1.0674; standard deviation, 0.0463; minimum, 1.012; and maximum, 1.145. The ratio was not significantly different from unity at 0.05. The small difference between actual and listed price is accounted for by the pharmacist buying in a larger package size,[9] and the fact the listed price includes a 11 per cent mark-up to the wholesaler, but if the patentee supplies directly to the pharmacist the actual price will likely be lower.

Next we turn to a comparison of Saskatchewan prices with those of New Brunswick.[10] The ratio of the patentee price in New Brunswick to that in Saskatchewan can be described as follows: mean, 1.0937; standard deviation, 0.0984; minimum, 0.9772; and maximum, 1.2721. The mean is not significantly different from unity, with a t-value of less than unity. These results suggest that there is close similarity between the patentee price in New Brunswick and Saskatchewan.[11] In other words, New Brunswick is being charged the top dollar for the patentee brand. Hence, we take great comfort in these similarities, since despite the fact there are considerable differences in the drug plans of New Brunswick and Saskatchewan, both present the opportunity for the patentee to charge a price akin to that which would prevail

without compulsory licencing, and this opportunity is apparently taken.[12]

One would expect that in a more competitive market that the patentee price would tend to be lower than the prices recorded in Saskatchewan and New Brunswick. For this purpose we chose British Columbia, in view of the discussion in sections II to IV. The results of the ratio of tha actual patentee price at which the British Columbia Pharmacare programme reimburses the pharmacist to the actual patentee price in Saskatchewan[13] can be summarized as follows: mean, 0.8201; standard deviation, 0.1571; minimum, 0.5722; and maximum, 0.9374. The inference to be drawn seem to be fairly clear: patentees, when operating in the more competitive British Columbia market follow different pricing strategies -- some attempt to lower their price to compete with the licensees while others maintain a price pretty close to that in Saskatchewan and New Brunswick, although somewhat lower. These data confirm our use of Saskatchewan and New Brunswick as patentee price havens.

An alternative source of information about the price that would be charged in the absence of compulsory licensing is the price in the U.S. (Gorecki, 1981, pp. 120-129). We therefore compared Saskatchewan formulary prices for patentee brands, which include a wholesale markup, with the U.S. price from the Drug Topics Redbook

for 1983, where the U.S. price was the price paid by the retailer (i.e., pharmacist) to the wholesaler.[14] The ratio of the U.S. wholesale price to the Saskatchewan wholesale price can be described as follows: mean, 1.2670; standard deviation, 0.2462; minimum, 0.9330; and maximum, 1.7249. An exchange rate of 1.2324 was used to convert U.S. to Canadian dollars. The ratio of U.S. to Saskatchewan prices was significantly different from unity at .05. If the Canadian dollar is treated as being par with the U.S. then the mean value of the ratio is 1.0346, and this is not significantly different from unity. Hence, if Canadian subsidiaries of U.S. firms price in nominal dollars (i.e., an exchange rate of 1.000), then U.S. and Canadian patentee prices will differ by the departure of the exchange rate from unity. There is some evidence consistent with this view. One study, which compared U.S. and Canadian prices for a sample of drugs for which no competition existed in either country, concluded, for 1982, that the "cost in Canada of these drugs was found to be about 21 per cent lower than if sold at U.S. list prices". (Canada, Department of Consumer and Corporate Affairs, 1983, p. 42)

Having discussed and described various data relating to patentee pricing in the absence of compulsory licensing and effective associated provincial government programmes designed to capture the benefit of compulsory licensing, a decision has to be made in the selection of the patentee price to be used and which province

to select. We decided to select Saskatchewan over New Brunswick data for the following three reasons: the data referred to October-December for actual prices, whereas New Brunswick referred to September 28, 1983 to March 23, 1984, but most of the provincial actual price data described in section B.2 referred to periods in 1983. Hence, Saskatchewan is more comparable; the drug price data for New Brunswick is derived from a formula assuming all pharmacists charge the agreed upon dispensing fee.[15] This may not be the case, thus imparting a downward bias to the drug cost; and the Saskatchewan figures represent the actual acquisition cost to the pharmacist whereas for New Brunswick there is a suggestion that the pharmacist gains a margin and hence the price we refer to is in some sense too "high". We decided to use Saskatchewan prices compared with U.S. because it was unclear how the exchange should be incorporated and only list prices were available for the U.S. Hence we use the actual price paid for the patentee brand in Saskatchewan by the province's Prescription Drug Plan as the price which would obtain were compulsory licensing not in existence in Canada -- P_P.

B.5 A Critical Examination of the Indices Used to Measure the Savings Due to Compulsory Licensing

In section 4.2 we defined three indices designed to measure various aspects of compulsory licensing. These indices were:

$$POTSAV = 1 - \frac{P_L}{P_P},$$

$$ACTSAV = (P_P - P_A)/(P_P - P_L),$$

and

$$UNSAV = 1 - ACTSAV.$$

In the previous sections we defined the three prices necessary to estimate these indices: P_P is the actual price in the no-substitution market in Saskatchewan between Oct-Dec 1983; P_A is the actual price paid by each provincial government reimbursement programme,[16] as well as HPI and thus represents a weighted average of patentee and licensee prices; and P_L is the licensee price for 1983. P_L and P_P are constant across markets but P_A will vary. In Table B-1 we present the three indices for the seven provincial markets and HPI. In section 4.3 these values were discussed at some length. Here our intention is to discuss some of the more important assumptions used in the construction of the indices.

An implicit assumption in our discussion of ACTSAV and UNSAV in the main text of the paper is that they are bounded by 0 and 1 because P_A is assumed to be less than P_P and greater than P_L. However, this did not always turn out to be the case. In a small number of instances for New Brunswick (5), Nova Scotia (1), and

Newfoundland (3), P_P was less than P_A. In such cases the P_A was set equal to P_P.[17] In the case of P_L this price was always less than P_A except for, not surprisingly, the hospital market -- HPI. However, a comparison of the two sets of prices did not show a large difference. The ratio of P_A from HPI to P_L for the seven drugs in our sample was on average 0.9556, with a minimum of 0.8786 and a maximum of 0.9894.[18] For HPI we set $P_A = P_L$ so that ACTSAV would not exceed 1.00.

A second possible problem might be that the patentee price, P_P, is measured for Oct-Dec 1983, but many of the estimates of ACTSAV refer to periods earlier than Oct-Dec 1983. While P_P was not available for the first nine months of 1983 formulary prices from Saskatchewan are available for Jan-June and July-Dec 1983. As we demonstrated in section B.4 actual and formulary prices for the patentee brands in Saskatchewan are quite close for the last three months of 1983. Hence, we compare formulary prices for 1983 for the patentee brand of our sample of seven drugs. The results are as follows:

	Patentee price per cap or tab in Saskatchewan Formulary, 1983	
	Jan-June	July-Dec
cimetidine 300 mg. tabs	0.2819	0.2819
indomethacin 25 mg. caps	0.2099	0.2247
naproxen 250 mg. tabs	0.3892	0.3892
propranolol 40 mg. tabs	0.1552	0.1552
methyldopa 250 mg. tabs	0.1314	0.1368
flurazepam 30 mg. caps	0.1116	0.1116
allopurinol 100 mg. tabs	0.0944	0.0944

Source Saskatchewan, Formulary, 16th edition, January 1983 and 17th edition, July 1983.

As can readily be observed the patentee prices as listed in the Saskatchewan Formulary for 1983 have remained unchanged for five of the drugs in our sample and increased slightly for two -- indomethacin 25 mg. caps, by 7.05 per cent, and methyldopa 250 mg. tabs, by 4.11 per cent. In view of the small change experienced, and then for only two drugs we feel the assumption of constant prices in 1983 is a reasonable view.

The licensee price is that to larger customers and as we noted in B.2 this is equal to the average price of the second licensee who provided data. It could therefore be argued that these licensee prices are too low in that only a small number of high

volume operations -- chains -- could take advantage of such prices by purchasing package sizes. This argument, however, has two flaws which suggest it is invalid for the drugs in our sample. First, the package sizes upon which the licensee prices are based are typically 1,000. The limited amount of evidence available indicates this is the typical size purchased for our sample of high volume drugs. In February 1984 five of the seven drugs in our sample had their prices based in the Ontario formulary on 1,000's[19] prices. In the case of cimetidine 300 mg. tabs, for example, the average pharmacy in Ontario purchased approximately 38 thousand in 1983.[20] In the January 1985 Newfoundland Interchangeable Drug Products Forumulary, in which six of the seven drugs in our sample are listed, five have prices based upon package sizes of 1,000.[21] Hence the assumption of package sizes of 1,000 seems reasonable for both small and large provinces and pharmacies.

The second reason that a package size of 1,000 is reasonable is that P_L is supposed to approximate what price would be charged in a well functioning market. As our discussion in sections II to IV of the paper make abundantly clear the retail drug market does not fit this description. It is likely that if price advertising were introduced along the lines suggested in Appendix C and section V that average pharmacy size would increase substantially, with consequent savings because larger package sizes could be purchased. This view is consistent with Cady's (1975, pp. 43-57) U.S. study, which compares states in the U.S. with and without

price advertising restrictions, and concludes "... that the regulation of advertising is positively associated with a significantly larger number of smaller pharmacies" (p. 48). Indeed, use of 1,000 might be too low a package size.

The estimate of ACTSAV and related indices in section 4.2 are a snapshot at a point in time. In a number of instances we estimated in section 4.2 ACTSAV based on P_A for 1984 but P_P and P_L as defined above on 1983 data. The evidence indicates the P_P for our sample of drugs increased in price in 1984: four between 5-8 per cent; two remained unchanged (cimetidine 300 mg. tabs and allopurinol 100 mg. tabs); and one, propranolol, increased by 5 per cent in January-July 1984 only to decline to the same level as July-December 1983 in the last half of 1984.[22] In contrast the sample of licensed drugs showed a fall in price, the mean ratio of P_L in 1983 to P_L in 1984 being 0.9287.[23] Whether ACTSAV will go up or down in 1984 therefore depends upon the degree to which P_A declines. However, we can say that: POTSAV will increase if P_P increased in 1984 and P_L decreased; and if ACTSAV is estimated using P_P and P_L for 1983, but P_A for 1984, and if P_A is lower than 1983, in part because P_L is lower in 1984, then the estimated ACTSAV will be biased upward.

The estimates of the three indices measuring various facets of compulsory licensing and associated provincial programmes

presented in Tables 13 and B-1 refer to the unweighted mean for the seven drugs in our sample. In some instances considerable variation in ACTSAV was found, as indicated by the standard deviations. This, combined with the fact that although the drugs in our sample were all high volume and multisource, some were more important than others, suggested that for some purposes a weighted average might be a useful statistic to calculate.

In estimating a weighted average of ACTSAV, POTSAV and UNSAV a problem arises over the weights to be used; in particular what quantities should be used and what prices. We decided to use P_P and three quantity weights: Canada-wide retail sales; Saskatchewan Prescription Drug Plan purchases; and B.C. Pharmacare purchases. The results are presented in Table B-2 for POTSAV and ACTSAV.

The weighted averages in Table B-2 are insensitive to the quantity weights used, as reading across a given row clearly demonstrates. In comparison with the unweighted results in Table B-1 we see essentially no difference for POTSAV, it is still about 0.65. In terms of the proportion of the actual dollar savings realised -- ACTSAV -- the unweighted and weighted results are broadly consistent, with Saskatchewan, Ontario, New Brunswick and HPI weighted and unweighted means differing by no more than a couple of percentage points. However, for B.C., Quebec, Newfoundland

and, especially, Nova Scotia, the weighted average is approximately six percentage points (11 in the case of Nova Scotia) higher than the unweighted mean. This primarily reflects the fact that for these four provinces the value of ACTSAV for cimetidine 300 mg. tabs was above the unweighted mean for all seven drugs and this drug carried a large weight in the sample of seven drugs.

The results discussed in sections III and IV for ACTSAV are concerned with how successful the various government programmes are in capturing the benefits, on average, across a sample of high volume multisource drugs. Hence an unweighted average was appropriate for answering the question did the plan work, on average, pretty well or not. What the weighted average tells us in comparison with the unweighted average, is that for one particularly important drug, cimetidine 300 mg. tabs, which experienced substantial increases in licensee competition in 1983 (see Table 6 and Canadian Drug Manufactures Association, 1984b) some provinces were apparently quicker to capture the benefits of compulsory licensing on that drug compared to the other six in our sample. A useful comparison is Ontario and Quebec for 1983, since both record a similar unweighted mean of ACTSAV. The lowest price in the Ontario formularies for cimetidine 300 mg. tabs in Jan.-June and July-Dec. was 0.2620 and 0.1500 respectively, per tab. In contrast, the corresponding figures for Quebec were 0.1900 and 0.1500. Hence, to the extent new high volume multisource drugs are coming onto the market some provinces are

able to reap the benefits more quickly on these drugs than others.

In terms of our discussion in sections III and IV of the text the inferences drawn and suggestions made would remain largely unaffected if the weighted rather than the unweighted mean were used. The rankings by ACTSAV are unchanged, except Nova Scotia ranks ahead of Newfoundland. Nevertheless, B.C. is more clearly the province most successful at gaining the benefits of compulsory licensing, with Saskatchewan and Quebec ranked about the same, with Ontario 10 percentage points behind, rather than being ranked about the same as Quebec. New Brunswick is still firmly ranked last.

In sum, in this Appendix we have tried to explain in some detail the construction of ACTSAV, UNSAV and POTSAV using P_L, P_A and P_P, by carefully specifying the derivation of these three prices and the assumptions implicit and explicit in their use. Hence, it is hoped the reader will have a greater appreciation and understanding of the indices used in sections III and IV of the paper.[24]

Notes to Appendix B

1 All provincial data relates to the provincial drug reimbursement programmes. See Table 2 for details.

2 Only the most popular dosage form and strength.

3 The other drugs were: captopril; diclopenac sodium; nifedipine; piroxicam; ranitidine; sulindac; metoprolol tartrate; and isosorbide dinitrate.

5 Only one price appeared, so it was not necessary to attach weight to various package sizes.

6 Using the approach suggested by Croxton et al. (1967, pp. 563-565) for non-independent samples.

7 Less the 11 per cent wholesale mark up included in the Saskatchewan Formulary price.

8 The data for both Saskatchewan and New Brunswick referred to late 1983 and in the case of New Brunswick, early 1984 as well.

9 For SOC drugs the prices listed in the Saskatchewan Formulary for those brands which did not win the SOC contract are typically for the smaller package sizes. In Saskatchewan there is actually acquisition cost pricing.

10 In order to compare like with like we have to be cognizant of the role of the wholesaler and the margins allowed. As noted above the list prices of the patentee in the Saskatchewan Formulary include a margin to the wholesaler, which may be reflected in the actual patentee price reimbursed by the government depending upon the mode of distribution; in New Brunswick if the pharmacist purchases direct from the manufacturer then the actual price reimbursed is the manufacturers list price, usually for the smallest available package size; however, if the pharmacist purchasers via a wholesaler then the latter is allowed a 20 per cent mark-up over the manufacturer's list price. Hence the ratios we estimate is the actual price paid in New Brunswick by the provincial drug reimbursement programme less 16.66 per cent in those cases where the drug is supplied via a wholesaler to the actual price paid in Saskatchewan less 9.09 per cent for the 11 per cent wholesale margin. The New Brunswick provincial drug reimbursement programme has a list of drug firms which supply direct to the pharmacist and those which supply via wholesaler. Only two of the drugs in the table were supplied via a wholesaler.

11 Despite the fact that Saskatchewan refers to Oct.-Dec. 1983 for actual prices, July-Dec. 1983 for formulary price and New Brunswick refers to Sept. 28, 1983 to March 23, 1984.

12 It would appear that in New Brunswick the margin spread is realized by the pharmacist. However, no data is available to confirm this impression gained by discussion with responsible officials in New Brunswick.

13 The numerator of the ratio includes, to some extent, a wholesale margin, while the denominator excludes wholesale margins, since the same procedure was followed as in fn. 10, the ratio is likely to be biased, somewhat, upward.

14 Either that suggested by the manufacturers or an independently determined average wholesale price.

15 See discussion of New Brunswick in Section B-2.

16 The only exception is Ontario for reasons stated in section B.2.

17 In the case of New Brunswick where P_A was frequently greater than P_P, we discussed in section B.3 the reasons for preferring Saskatchewan to New Brunswick as the source for patentee prices.

18 In the data available at HPI prices were quoted in the tenders for various package sizes -- 100's, 1,000's, etc. When comparing HPI P_A with P_L we selected the same package size for each drug, typically 1,000's.

19 The list of five is taken form Gordon (1984, Appendix A, n.p.). It is noteworthy that one of the excluded drugs, indomethacin 25 mg. caps, had total sales in Ontario in 1983 that exceeded flurazapam 30. mg. caps, (listed in 1,000's) and hence should have perhaps been included. (Total sales figures based on data supplied by the Ontario Ministry of Health.) Finally, the other excluded drug, allopurinol 100 mg. tabs had its price adjusted downward in February 1984 based on 100.

20 In Ontario, for 1983, the average number of units (caps or tabs) purchased per pharmacy, for the drugs in our sample, was as follows:

cimetidine 300 mg. tabs	38,434
indomethacin 25 mg. caps	8,581
naproxen 250 mg. tabs	22,525
propranolol 40 mg. tabs	35,611
methyldopa 250 mg. tabs	25,293
flurazepam 30 mg. caps	6,834
allopurinol 300 mg. tabs	5,102

where the allopurinol dosage is 300 mg. tabs not 100 mg. tabs. The data on quantity was provided by the ODB. Since the ODB forms 45 per cent of the Ontario market, this quantity is multiplied by 1.222 to derive the total consumption for Ontario for 1983. The number of pharmacies at 1,826 was provided by the Ontario Ministry of Health for 1983/84. The number of units sold per pharmacy may differ from those reported above depending upon the patterns of drug utilization between the ODB and non-ODB population.

21 The drug not listed as interchangeable was flurazepam 30 mg. caps, while allopurinol 100 mg. tabs, although listed, was priced based on a smaller package size. It should be noted that of the four drugs listed in both the 1983 and Jan-July 1985 Newfoundland formulary all had their prices based on 1,000's in 1985 (except allopurinol 100 mg. tabs) while in 1983 only two were based on 1,000's -- propranolol 40 mg. tabs and cimetidine 300 mg. tabs. The move to larger more realistic package sizes was, no doubt, part of the Newfoundland's government use of more realistic prices discussed in section 4.3 of the paper. Details of the package size upon which Newfoundland bases its prices may be found in each formulary.

22 Using formulary prices for the patentee from Saskatchewan and comparing July-Dec 1983 with prices in the Jan-June 1984 and July-Dec 1984 formularies.

23 Based on the same sources as discussed in section B.3.

24 In section V of the paper it is stated that about 50 per cent of the potential dollar savings are realised because of compulsory licensing and associated government policies. This inference is still valid if the weighted value of ACTSAV is used. The results are as follows:

	Weight (1)	WEIGHTED ACTSAV (2)	(1)·(2) (3)
Hospital market	0.20	1.00	0.2000
Retail market	0.80	-	-
Newfoundland	0.0277	0.2741	0.0076
Prince Edward Island	0.0048	0.2000	0.0010
Nova Scotia	0.0418	0.2979	0.0125
New Brunswick	0.0352	0.0050	0.0002
Quebec	0.1881	0.5066	0.0953
		(0.3388)	(0.0637)
Ontario	0.2676	0.4104	0.1098
		(0.2289)	(0.0613)
Manitoba	0.0255	0.5000	0.0128
Saskatchewan	0.0379	0.5220	0.0198
Alberta	0.0691	0.2000	0.0138
British Columbia	0.1006	0.6047	0.0608
Weighted average =	-	-	0.5336
			(0.4535)

This tabulation corresponds to that in text footnote 134 except that column (2) is the weighted value of ACTSAV from Table B-2

(where Saskatchewan Quantity Weights are used). The weighted and unweighted averages of Prince Edward Island, Manitoba and Alberta are assumed to be the same. For Ontario and Quebec the weighted value of ACTSAV for the whole province (the number in parentheses) is assumed to bear the same relationship to the unweighted mean as the corresponding values for the ODB -- the numbers not in parentheses. Hence, for example, the 0.2289 weighted value of ACTSAV for the whole province of Ontario is derived as follows: (0.4104/0.4053) . 0.2261 = 0.2289.

Table B-1

The Potential, Actual, and Still to be Realized Savings Due to Compulsory Licensing and Associated Provincial Government Reimbursement Programmes for Seven Multisource Drugs, for Seven Provincial Drug Reimbursement Programmes and Hospital Purchasing Incorporated, 1983

Market	POTSAV[b]	ACTSAV[b]	UNSAV[b]
	Average[c] (Standard Deviation)		
British Columbia (1983)	0.6538 (0.094)	0.5447 (0.103)	0.4553 (0.103)
Saskatchewan (Oct-Dec, 1983)	0.6538 (0.094)	0.5213 (0.062)	0.4787 (0.062)
Ontario (1983)	0.6538 (0.094)	0.4053 (0.144)	0.5947 (0.144)
Quebec (1983 and Jan-June 1984)	0.6538 (0.094)	0.4405 (0.236)	0.5595 (0.236)
New Brunswick (Sept. 28 1983-March 31, 1984)	0.6538 (0.094)	0.0193 (0.031)	0.9807 (0.031)
Nova Scotia (Oct-Dec, 1983)	0.6538 (0.094)	0.1854 (0.181)	0.8146 (0.181)
Newfoundland (April-Sept, 1983)	0.6538 (0.094)	0.2262 (0.238)	0.7738 (0.238)
Hospital Purchasing Incorporated[a] (1983/84)	0.6538 (0.094)	1.000 (0.000)	0.0000 (0.000)

a Should be read as the year ending June 1984 although this did vary somewhat.

b These are defined in the text.

c Unweighted average of the index across seven drugs. See Table 5 for full details of sample of drugs.

Source Data provided by various provincial governments, licensees, HPI, and the Saskatchewan Formulary, various issues.

Table B-2

The Potential and Actual Savings Due to Compulsory Licensing and Associated Provincial Government Reimbursement Programmes for Seven Multisource Drugs,[c] for Seven Provincial Drug Reimbursement Programmes and Hospital Purchasing Incorporated, 1983, Measured Using Weighted Averages

Market	ACTSAV[b]		
	Canada Quantity Weights	Saskatchewan Quantity Weights	B.C. Quantity Weights
	Weighted Average[d]		
British Columbia (1983)	0.6070	0.6047	0.6065
Saskatchewan (Oct-Dec, 1983)	0.5185	0.5220	0.5212
Ontario (1983)	0.4057	0.4104	0.4074
Quebec (1983 and Jan-June 1984)	0.5153	0.5066	0.5097
New Brunswick (Sept. 28 1983-March 31, 1984)	0.0081	0.0050	0.0070
Nova Scotia (Oct-Dec, 1983)	0.2908	0.2979	0.2876
Newfoundland (April-Sept, 1983)	0.2672	0.2741	0.2610
Hospital Purchasing Incorporated[a] (1983/84)	1.0000	1.000	1.0000
POTSAV[e]	0.6573	0.6524	0.6555

a Should be read as the year ending June 1984 although this did vary somewhat.
b These are defined in the text.
c See Table 5 for full details of the sample of drugs used.
d Drug sales were used as weights. The price selected was P_p and three different quantities: Canada-wide retail; Saskatchewan Prescription Drug Programme; and B.C. Pharmacare.
e POTSAV does not vary by market.

Source Data provided by various provincial governments, licensees, HPI, and the Saskatchewan Formulary, various issues.

APPENDIX C

SUGGESTIONS FOR FURTHER LOWERING RETAIL DRUG PRICES

These suggestions, renumbered and, in one instance, slightly changed, concerning retail drug prices are taken from Gorecki (1981, pp. 187-189).

1. The standards and quality of professional service supplied by the profession of pharmacy should be set and enforced by the professional body in consultation with the provincial Minister of Health.

2. The dispensing fee should be defined in such a way that it is a standard service provided and monitored by the pharmacists' professional body in consultation with the provincial Minister of Health.

3. All restrictions on the disclosure of the price of dispensing fees, either over the phone, in the store, in newspapers, television and radio should be removed from provincial statutes and regulations.

4. The quantity dispensed by a pharmacist on receipt of a prescription should be that authorized by the physician, whether it is for 30, 60 or 100 days, for all sectors of the marketplace.

5. Provincial governments should consider, where practical, using the forces of the market for those currently receiving drugs free of charge so that greater utilization of pharmacies offering lower priced dispensing fees is made.

6. Pharmacists should be expressly permitted to provide information on drug prices over the phone or in the store; formularies should be available for inspection in the pharmacy (where the province publishes such documents); proposals for dissemination of pricing rules, which do not mention individual brands or generic names, used by pharmacists should be permitted.

7. Provincial governments should promote lower drug prices for all sectors of the market, not just the government reimbursement programme, by the use of some or all of the following: certifying therapeutic equivalence of different brands of the same drug; insuring that the physician and pharmacist bear no legal liability in selecting among these brands; mandatory price selection; mandatory product selection; formularies based on "realistic" prices; printing only a single price for multisource drugs; actual acquisition cost pricing; and tendering systems.

8. Provincial governments should seriously consider making physicians aware of the interchangeability of brands, quality control and price of different brands so that they be fully aware of the implications of no-substitution prescriptions.